

Massachusetts Department of Public Health

Epidemiology and Laboratory Capacity for

Infectious Diseases

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APPLICATION

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Principal Investigator

Alfred DeMaria, Jr., MD

State Epidemiologist

305 South Street
Jamaica Plain, MA 02130
(617) 983-6800

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Each section contains the following components: a) *Background, Need and Understanding*, b) *Operational Plan*, and c) *Measures of Effectiveness*. Budget narratives for each component can be found in a separate document included in the application.

SECTION 1

APPLICATION OVERVIEW

a. Program components addressed in this application

The Massachusetts Department of Public Health (MDPH) will be addressing the following 15 component activities in this application:

- 1: National Electronic Disease Surveillance System**
- 2A & 2B: OutbreakNet**
- 2C: FoodCore**
- 2D & 2E: PulseNet**
- 2F: CaliciNet**
- 2G: NARMS**
- 4: Healthcare-Associated Infections**
- 5: Arboviral Diseases**
- 6: Lyme Disease**
- 8: Influenza**
- 12A: Rabies**
- 12C: Tickborne Diseases**
- 12D: Waterborne Diseases**

b) Information on Jurisdiction

Massachusetts population size, demographic characteristics, and racial/ethnic makeup.

TOTAL MASSACHUSETTS POPULATION 2010	
6,547,629	
SEX	
Male	3,166,628
Female	3,381,001
AGE	
Under 18 years	1,418,923
18 and over	5,128,706
20 to 24 years	475,668
25 to 34 years	845,141
35 to 49 years	1,402,583
50 to 64 years	1,300,370
65 and older	902,724
RACE	
One race	6,375,626
White	5,265,236
African-American	434,398

Asian	349,768
AIAN	18,850
NHPI	2,223
Some other race	305,151
Two or more races	172,003
HISPANIC ORIGIN	
Hispanic or Latino	627,654
Not Hispanic or Latino	5,919,975
Sources: US Census Bureau, 2010 Census Summary File	

Geographic distribution:

Massachusetts is the fourteenth most populous state in the nation, with over six million people distributed over 351 cities/towns. Only five of these cities/towns have populations greater than 100,000, while approximately 270 have populations less than 20,000 (US Census).

Data for Massachusetts show that the five most populous cities or towns and their 2010 Census counts are Boston, 617,594; Worcester, 181,045; Springfield, 153,060; Lowell, 106,519; and Cambridge, 105,162. Boston grew by 4.8 percent since the 2000 Census. Worcester grew by 4.9 percent, Springfield grew by 0.6 percent, Lowell grew by 1.3 percent, and Cambridge grew by 3.8 percent.

The largest county is Middlesex, with a population of 1,503,085. Its population grew by 2.6 percent since 2000. The other counties in the top five include Worcester, with a population of 798,552 (increase of 6.3 percent); Essex, 743,159 (increase of 2.7 percent); Suffolk, 722,023 (increase of 4.7 percent); and Norfolk, 670,850 (increase of 3.2 percent).

Disease burden

Please see below table for a subset of notifiable, communicable diseases for 2010

Selected Notifiable Conditions	# Confirmed Cases	# of Probable Cases	# of Suspect Cases
Amebiasis	39	40	1
Babesiosis	82	4	105
Campylobacteriosis	1084	0	13
Cryptosporidiosis	174	0	4
Giardiasis	743	0	4
Hepatitis A	50	0	4
Hepatitis B, acute	77	0	39
Hepatitis B, chronic	548	1247	120
Hepatitis C, acute	16	0	166
Hepatitis C, chronic	4612	3217	59
Human Gran. Anaplasmosis	80	62	255
Invasive <i>Haemophilus influenzae</i>	94	0	0

Invasive group A streptococcus	188	0	6
Invasive meningococcal disease	8	0	3
Invasive pneumococcal disease	640	0	16
Legionellosis	135	0	23
Listeriosis	27	0	2
Lyme disease	2622	1003	4436
Measles	3	0	0
Mumps	9	0	39
Pertussis	330	0	1
Salmonellosis	1263	0	1
Shiga toxin-producing organism	62	16	15
Shigellosis	213	0	2
Tularemia	3	0	0
<i>Vibrio species</i>	53	0	3

Massachusetts local public health operates through 351 individual city and town jurisdictions, with a rapidly diminishing response capacity for public health activities. Most of the 351 cities/towns have part-time boards of health with only approximately two dozen having full time health departments. In about 20% of these jurisdictions, selectmen function as the local public health authority.

Epidemiology

The Division of Epidemiology and Immunization within the Massachusetts Department of Public Health (MDPH) Bureau of Infectious Disease (BID) is tasked with surveillance, response and control activities for all zoonotic, foodborne and waterborne illnesses; meningitis, all BT agents, hepatitis (A,B,C), antibiotic resistant organisms, health care associated infections (HAI) and vaccine preventable diseases.

Laboratory

The Bureau of Laboratory Sciences (BLS) is a technical resource for MDPH and supports multiple Bureaus of MDPH and includes the Enterics, PFGE, Food, Molecular, Dairy, Serology and Virus Isolation Laboratories.

Health Information Systems

The MDPH Office of Integrated Surveillance and Informatics Services (ISIS) oversees surveillance activities and informatics resources for the divisions and programs within the BID. These include the Divisions of Epidemiology and Immunization, STD Prevention and AIDS Surveillance, TB Prevention and Control, and the Refugee and Immigrant Health Program (RIHP). ISIS enhances and optimizes the collection and distribution of infectious disease surveillance data and promotes standards-based electronic reporting of notifiable disease data by hospital laboratories, electronic health records, and other public health partners. ISIS develops,

deploys and maintains the Massachusetts Virtual Epidemiologic Network (MAVEN), and oversees Electronic Laboratory Reporting (ELR) and Health Information Exchange (HIE) efforts as they relate to notifiable disease reporting and surveillance activities.

There are approximately 90 notifiable diseases in Massachusetts. Responsibility for case investigation and follow up of the majority of these diseases falls to the 351 independent jurisdictions within the state. MAVEN enables state and local boards of health (LBOH) to share public health, laboratory, and clinical data efficiently and securely over the Internet. As of September 2011, approximately 200 of the 351 LBOHs are utilizing MAVEN. In July 2011, MDPH promulgated regulations mandating all LBOHs utilize MAVEN for their surveillance and case management needs. The Bureau expects 95% compliance by the end of 2012.

MAVEN allows the direct reporting of notifiable diseases by clinicians and LBOH, appropriate data-sharing between state and LBOH, and improved data management and analysis. It captures all relevant information on notifiable conditions and data elements are easily added or modified to capture additional information as circumstances change, such as in a pandemic event or an outbreak of foodborne illness. The ELR system is the conduit for all electronic data sent to MAVEN.

The MDPH BLS Informatics Office supports critical public health laboratory IT functions, including evaluation and implementation of new diagnostic testing methods, development of IT capacity to respond to new public health events and emergencies, and enhancement of communications and data transfer between the BLS and its partners. Each BLS laboratory program works closely with its corresponding BID disease prevention program on joint surveillance projects, investigations of outbreaks and clinical cases, and other collaborative programmatic initiatives.

As a result of the strong collaboration, the BID and the BLS jointly developed the Electronic Laboratory Communication and Reporting system to support the electronic exchange of information between public health agencies and clinical partners, including hospitals, laboratories, providers and electronic health records. This was deployed in October 2004 and is a secure web-based system that is utilized by both BLS and BID.

State and federal resources have been integrated to support MAVEN and ELR efforts. Funding from various CDC Cooperative Agreements, including ELC-ACA and HITECH, PHEP, STD, and TB have been leveraged to promote a sustainable surveillance infrastructure that provides for the needs of the various categorical programmatic areas within the BID. Similarly, funding provided from ELC-ACA and PHEP to the BLS allows them to continue to provide a high level of testing options necessary for outbreak detection and response. The PHEP cooperative agreement provides a small amount of funding to the Epidemiology Program, which supports general emergency preparedness in regards to infectious disease response.

Funding through ELC-ACA allows for a more flexible approach in filling gaps identified at MDPH, while funding from the ELC-Program Components is more targeted. Both are necessary to accomplish the goals of epidemiology, the laboratory and health information exchange.

Personnel funded through all sources, whether state or federal, work as a team and are typically cross-trained in many areas of response, allowing for a flexible approach to surveillance, communication, disease detection and response.

c) Progress to enhance integration

The BLS, the BID and the Food Protection Program (FPP) of the Bureau of Environmental Health reside in the same building. Face-to-face interactions are frequent and communication is comprehensive and extensive. Current staff have been designated to ensure the integration of the ELC-funded categorical programs. One example of successful integration is the Working Group on Foodborne Illness Control (WGFIC). The WGFIC was established in 1986 and consists of epidemiologists, laboratorians and environmental specialists who meet regularly to ensure that foodborne outbreak investigations are properly coordinated. ELC funded positions can be found in the Epidemiology Program, the BLS and the FPP. Epidemiologists from the Epidemiology Program are all cross-trained in the diseases under their responsibility and also in disease response for vaccine-preventable diseases as needed. All infectious disease response clearly requires the integration of disease surveillance systems at the state and local level and laboratory systems in hospitals, commercial laboratories and the state public health laboratory. Leadership in these areas at MDPH are clearly engaged and committed to improving coordination among all surveillance participants.

d) Challenges

The MDPH personnel recruitment requires a minimum of 3-4 weeks to identify a selected candidate. Fortunately most of the positions requested in this cooperative agreement are already filled with trained and experienced staff. While contractual personnel positions can be hired quickly, they still need to undergo a training process dependent on their skill level at hire. Laboratory personnel require a minimum of three weeks for initial training to establish competency in testing methods. Newly hired epidemiologists require a longer training period for some aspects of the position but typically come with an MPH degree. In addition, many epidemiologists are hired from a pool of applicants with internship experience at MDPH and LBOH and some can contribute almost immediately.

It is our goal to ensure that unobligated funds remaining at the end of the budget and project period are kept to a minimum.

e) Governance, Integration, Tracking, and Reporting

i. **Governance Team**

The ELC Governance Team for Massachusetts will consist of the following individuals:

Principal Investigator

Alfred DeMaria, Jr. MD

State Epidemiologist and Medical Director

Bureau of Infectious Disease

MDPH
305 South Street, Jamaica Plain, MA 02130
alfred.demaria@state.ma.us
617-983-6551

Epidemiology Lead
Patricia Kludt, MPH
Epidemiology Program Coordinator
Bureau of Infectious Disease Response and Services
MDPH
305 South Street, Jamaica Plain, MA 02130
patricia.kludt@state.ma.us
617-983-6832

Laboratory Lead
Linda Han, MD, MPH
Director, Bureau of Laboratory Services
William A. Hinton State Laboratory Institute
MDPH
305 South Street, Jamaica Plain, MA 02130
Linda.han@state.ma.us
617-983-4362

IT/Informatics Lead
Gillian Haney, MPH
Director, Office of Integrated Surveillance and Informatics Services
MDPH
305 South Street, Jamaica Plain, MA 02130
Gillian.haney@state.ma.us
617-983-6863

ii. Epidemiology, laboratory and health information systems integration

The MDPH is well integrated when it comes to epidemiology, laboratory and health information systems. Because the ELC cooperative agreement cover so many programs integration is important to reach critical goals. To that end, meetings are held monthly to discuss budget issues pertaining to the ELC cooperative agreements, including carryover, redirection and supplemental requests. Participants at this meeting include coordinators of all the components of the cooperative agreements. Attendance is by phone or in person, and includes representation from the laboratory, food protection program, epidemiology, immunization, IT and health informatics. These meetings will continue, as they are an important way to discuss shared concerns and reinforce integration efforts across the laboratory, epidemiology and health information systems.

Because all individuals involved in the ELC cooperative agreements are co-located in one building, meetings regarding general oversight, planning, review and agreement on annual

continuation applications are usually held to specifically to deal with issues related directly to the ELC cooperative agreements and include the individuals who are now named as part of the newly formed Governance Team. This process will now be formalized and meetings of Program Staff with the Governance Team will be held on a quarterly basis and more frequently as needs are identified. The team will discuss ELC plans, activities, awards, progress reports, and metrics.

The first meeting of the Governance Team will occur within two weeks of receiving the Notice of Grant Award for this funding opportunity. Subsequent meetings will be scheduled at that time. A specific budget request for travel to a meeting in 2012 for members of the Governance Team or their specific designees will be included in the Application Overview budget. From time to time there are restrictions placed on travel. If travel is specifically requested in a cooperative agreement and it is approved, then it is more likely that travel will be allowed.

iii. Cross-cutting metric

The Office of Integrated Surveillance and Informatics Services (ISIS) develops, deploys and maintains the PHIN-compliant integrated and interoperable Massachusetts Virtual Epidemiologic Network (MAVEN). MAVEN allows the direct reporting of notifiable diseases by clinicians and local public health, appropriate data-sharing between state and local public health, and improved data management and analysis. It captures all relevant information on notifiable conditions and data elements are easily added or modified to capture additional information as circumstances change, as in a pandemic event or an outbreak of foodborne illness. The ELR system is the conduit for all electronic data sent to MAVEN.

At its core, MAVEN is a person-based system that allows for multiple disease events to be linked to an individual. This enables sharing of complete demographic information across the person's disease events, as appropriate. It also allows for a more complete and accurate view of co-morbidity and reduces the burden of duplicative data entry. Further, MAVEN has a de-identified functionality capturing critical non-person-based surveillance data, which includes rapid influenza results, foodborne illness complaints, rabies exposures, and aggregate influenza reports from sentinel surveillance sites. BID has configured an outbreak management module to capture data on clusters and outbreaks identified through traditional means, ELR, and potentially syndromic surveillance efforts. The module interfaces with the event level data in MAVEN so that persons and environmental data may be linked.

MAVEN is configurable at the local level for disease planning and investigation, form development, survey design, and data collection purposes. Modifications are user-driven and directed by subject matter experts. The application allows appropriate data-sharing between state and local public health, direct access to data by epidemiologists, and improved data management and analysis.

The outbreak module in MAVEN will be the primary means for collecting the information requested in the table provided in this FOA.

The only barriers we anticipate will be the ability to identify the outbreaks investigated by ELC supported staff versus the outbreaks investigated by non-ELC supported staff. All

epidemiologists are cross-trained in all aspects of disease response. Outbreaks are investigated by a two person team. These teams are sometimes comprised solely of ELC supported staff but not always as outbreak investigations are assigned according to available time. We will make every effort, however, to identify outbreak investigators by their funding source.

iv. ELC Success Stories

- In 2010, Massachusetts performed aerial spraying of pesticides over ~280,000 acres to decrease the risk associated with exposure to mosquitoes potentially infected with eastern equine encephalitis virus. This decision was based on laboratory findings provided by MDPH's arbovirus program with support from ELC funds.
- In an effort to provide more advanced surveillance and epidemiology training, the seven-day "Epidemiology-in-Action" program was provided in Massachusetts by CDC and Emory University staff May 17 – May 25, 2005.
- The *Guide to Surveillance, Reporting and Control*, originally developed and published in 2001, also with the assistance of ELC funding, was revised and published in 2006.
- A campaign regarding community associated MRSA resulted in the development of educational materials that are co-branded with CDC and still available at <http://www.cdc.gov/mrsa/library/posters.html#consumerEd>.
- The successful implementation of Electronic Laboratory Reporting. As of September 2011, 61 of the 73 hospital laboratories and two commercial laboratories are fully certified to transmit results using ELR.
- The development, deployment and maintenance of the Massachusetts Virtual Epidemiologic Network (MAVEN). As of September 2011, approximately 200 of the 351 local boards of health are utilizing MAVEN for web based disease reporting.
- Numerous outbreaks over the years, both multi-state and in-state, identified through PFGE, most notably a listeriosis outbreak due to pasteurized milk from a local dairy.
- A second edition of *Tickborne Diseases in Massachusetts: a physician's reference manual* was developed and printed in 2009 with the assistance of ELC funding. Over 6,000 manuals have been distributed in MA and a link is included on the CDC website <http://www.cdc.gov/lyme/resources/index.html>. These materials have also been adapted in other jurisdictions such as ME and NY. http://www.mass.gov/Eeohhs2/docs/dph/cdc/lyme/tickborne_diseases_physician_manual.pdf

v. ELC Value

ELC has been an invaluable and irreplaceable source of funding for many MDPH public health activities related to infectious diseases. Over this particular project period, funding for personnel alone has provided for 10-15 positions each year to work on many areas of concern including but not limited to health information systems, influenza, foodborne illness, West Nile Virus, Lyme disease, health care associated infections, and antibiotic resistance. ELC funded epidemiologists make up more than one third of the MDPH Epidemiology Program. The loss of ELC funding would severely impact epidemiology, laboratory and health information systems within MDPH. Based on the MDPH Hinton State Laboratory Institute's participation in the 2011 CDC/ APHL

Influenza Testing Capacity Modeling Project, the loss of even one position would have a major impact on laboratory testing capacity. ELC currently supports one of four staff performing influenza RT-PCR assays. PFGE testing would be another area of the laboratory which depends heavily on ELC funding. PFGE results are essential to indicate relatedness among organisms. Epidemiologists rely heavily on this data to identify outbreaks and assign resources for investigations. Without this capability, more epidemiology resources would be needed to identify clusters through more time-consuming methods. Unfortunately, without ELC funding epidemiology resources would also be critically reduced leading to unidentified outbreaks and the inability to fully participate in outbreaks that are identified. The loss to health information systems would impact our ability to maintain our internet based surveillance system (MAVEN) and train our local health partners in its. It would impede forward progress in electronic laboratory reporting.

Requests:

Massachusetts requests funding for four people to travel to the ELC meeting in the spring of 2012 and part-time support of a business manager for the ELC grant.

ATTACHMENT 1

NATIONAL ELECTRONIC DISEASE SURVEILLANCE SYSTEM (NEDSS)

a) Background, Need and Understanding

With a population of over 6.5 million, Massachusetts is the fourteenth most populous state in the nation. The state is comprised of 351 independent cities and towns and has no county health department infrastructure. Only five of these cities/towns have populations greater than 100,000, while approximately 270 have populations less than 20,000 (US Census).

The Office of Integrated Surveillance and Informatics Services (ISIS) oversees surveillance activities and informatics resources for the divisions and programs within the Bureau of Infectious Disease (BID). These include the Divisions of Epidemiology and Immunization, STD Prevention and AIDS Surveillance, TB Prevention and Control, and the Refugee and Immigrant Health Program (RIHP). ISIS enhances and optimizes the collection and distribution of infectious disease surveillance data and promotes standards-based electronic reporting of notifiable disease data by hospital laboratories, electronic health records, and other public health partners. ISIS develops, deploys and maintains the Massachusetts Virtual Epidemiologic Network (MAVEN), and oversees Electronic Laboratory Reporting (ELR) and Health Information Exchange (HIE) efforts as they relate to notifiable disease reporting and surveillance activities.

State and federal resources have been integrated to support the MAVEN and ELR efforts. Funding from various CDC Cooperative Agreements, including ELC ACA and HITECH, PHEP, STD, and TB have been leveraged to promote a sustainable surveillance infrastructure that provides for the needs of the various categorical programmatic areas within the BID. The ELC Cooperative Agreement provides principal support for two key positions, the *NEDSS (MAVEN) Project Manager* and *NEDSS (MAVEN) Lead* who provide on-going support for the implementation and continued enhancement of MAVEN and ELR. The Project Manager also provides technical and programmatic oversight of the deployment of MAVEN. A key objective during the first year of this Cooperative Agreement is the deployment of MAVEN across the 351 jurisdictions with the goal of achieving 95% implementation by the end of 2012.

There are approximately 90 notifiable diseases in Massachusetts. ISIS receives and triages approximately 150,000 individual reports. The table below depicts case counts for a subset of these diseases for 2010.

Selected Notifiable Conditions	# Confirmed Cases	# of Probable Cases	# of Suspect Cases
Amebiasis	39	40	1
Babesiosis	82	4	105
Campylobacteriosis	1084	0	13
Cryptosporidiosis	174	0	4
Giardiasis	743	0	4
Hepatitis A	50	0	4

Hepatitis B, acute	77	0	39
Hepatitis B, chronic	548	1247	120
Hepatitis C, acute	16	0	166
Hepatitis C, chronic	4612	3217	59
Human Granulocytic Anaplasmosis	80	62	255
Invasive <i>Haemophilus influenzae</i>	94	0	0
Invasive group A streptococcus	188	0	6
Invasive meningococcal disease	8	0	3
Invasive pneumococcal disease	640	0	16
Legionellosis	135	0	23
Listeriosis	27	0	2
Lyme disease	2622	1003	4436
Mumps	9	0	39
Pertussis	330	0	1
Salmonellosis	1263	0	1
Shiga toxin-producing organism	62	16	15
Shigellosis	213	0	2
Tularemia	3	0	0
<i>Vibrio species</i>	53	0	3

Primary responsibility for case investigation and follow up of the majority of these diseases legally falls to the 351 independent jurisdictions within the state; the state health department has assumed a supporting role for individual case investigations and a coordinating role in outbreak situations. However, fewer than 25 jurisdictions have full time health departments and in about 20%, selectmen function as the local public health authority. This has required the state to take on more of the burden of direct case investigation and further heightened the need for a statewide integrated surveillance case management system that can be used by both state and local officials for a coordinated response.

To meet state and local surveillance and case management needs, ISIS deployed a PHIN-compliant integrated and interoperable system in September 2006: MAVEN. MAVEN enables state and local health departments to share public health, laboratory, and clinical data efficiently and securely over the Internet. The system fully interfaces with the Department's ELR and electronic health record (EHR) reporting initiatives and can exchange information with CDC via standards-based electronic messaging. ISIS utilizes the PHIN Implementation Guides and documentation to ensure standards based development for MAVEN.

MAVEN allows the direct reporting of notifiable diseases by clinicians and local public health, appropriate data-sharing between state and local public health, and improved data management and analysis. It captures all relevant information on notifiable conditions and data elements are easily added or modified to capture additional information as circumstances change, such as in a pandemic event or an outbreak of foodborne illness. The ELR system is the conduit for all electronic data sent to MAVEN.

At its core, MAVEN is a person-based system that allows for multiple disease events to be linked to an individual. This enables sharing of complete demographic information across the

person's disease events, as appropriate. It also allows for a more complete and accurate view of co-morbidity and reduces the burden of duplicative data entry. Further, MAVEN has a de-identified functionality capturing critical non-person-based surveillance data, which includes rapid influenza results, foodborne illness complaints, rabies exposures, and aggregate influenza reports from sentinel surveillance sites. The BID has configured an outbreak management module to capture the clusters data identified through traditional means, ELR, and potentially syndromic surveillance efforts. The module interfaces with the event level data in MAVEN so that persons and environmental data may be linked.

MAVEN is configurable at the local level for disease planning and investigation, form development, survey design, and data collection purposes. Modifications are user-driven and directed by subject matter experts. The application allows appropriate data-sharing between state and local public health, direct access to data by epidemiologists, and improved data management and analysis.

Once fully deployed at the state and local level, MAVEN will replace paper-based methods of data exchange. MAVEN allows automatic generation of workflows and questionnaires: receipt of an ELR results in a questionnaire that sits in queue, awaiting response from an appropriate investigator at the state or local level. When users log on, they are prompted with the cases currently in their respective workflows. Once the investigation is complete, a new workflow is called that sends the information about that case into the queue for the next stage of review.

MAVEN has built-in algorithms to identify reports that require the immediate notification of a health professional and to identify excess reports of illness that might signal an aberration from normal disease patterns. This system has automatic (24/7/365) notification of state and local officials of any event requiring their attention.

In addition, MAVEN has a de-identified module that will allow the tracking of individuals exposed to suspect rabid animals, animal test results and an aggregate influenza reporting database to monitor seasonal and pandemic influenza. Eventually this module will also be utilized to capture the foodborne illness complaints and incidents.

MAVEN currently supports the surveillance and case management needs for all notifiable conditions at the state and local level except STDs and HIV/AIDS, as well as the case management needs of the RIHP. ISIS plans to deploy the STD module in early 2012. ISIS is focused on deploying MAVEN to local boards of health (LBOH), a process which involves significant training and support. As of September 2011, approximately 200 of the 351 LBOH are utilizing MAVEN. In July 2011, MDPH promulgated regulations mandating all LBOHs utilize MAVEN for their surveillance and case management needs. Years 2-5 of this Cooperative Agreement will be focused on expanding MAVEN's capacity to meet additional case investigation requirements from LBOH based on detailed requirements gathering. In addition to specific disease surveillance enhancements, new functionality will include the ability to track animal exposures and health education interventions.

Several other states and jurisdictions are also developing and implementing surveillance and case management systems that utilize the same core product as MAVEN. We have formed a user group in order to collaborate in terms of resource and module sharing, and knowledge transfer. In addition, the city of Boston purchased the same core product as MAVEN, the Boston Surveillance System (BoSS); ISIS is working with the Boston Public Health Commission (BPHC) to ensure that successful real-time data exchange with MAVEN occurs.

The BID's PHIN-compliant ELR infrastructure establishes secure, electronic messaging between clinical laboratory applications with MAVEN. Clinical laboratories may currently transmit data on all notifiable conditions. Participants utilize a web based user interface to create a mapping between BID selected LOINC and SNOMED codes and their local equivalents. These mappings are used to translate native codes into their LOINC and SNOMED equivalents before data persist into the BID data store. Institutions may transmit messages using the HL7 2.3.1 ORU RO1 or a BID developed message format that is transformed into HL7 2.3.1. This same infrastructure supports the transmission of hospital ED data for syndromic surveillance activities and data derived from electronic medical records. In 2011 in order to meet Meaningful Use requirements, the BID upgraded this infrastructure to support HL7 2.5.1. In addition, the BID ensured the capability of transforming existing HL7 2.3.1 to HL7 2.5.1.

There are a total of 73 hospital laboratories in Massachusetts. In July 2008, MDPH passed regulations mandating the use of its ELR infrastructure for reporting notifiable conditions. As of September 2011, 61 of the 73 hospital laboratories are fully certified to transmit results using ELR and the remaining hospitals are in various stages of the implementation process. Two commercial laboratories are fully certified.

As a partner in one of the CDC-awarded Centers for Excellence in Informatics, MDPH is actively engaged in leveraging existing technical solutions, principally MDPH's ELR infrastructure, to electronically receive pertinent health information to support case investigations. As described in the MMWR (MMWR: 2008;57:373-6), the *Electronic Support for Public Health (ESP)* initiative has successfully developed algorithms to automatically send key clinical and demographic information to the BID for the following notifiable diseases: syphilis, gonorrhea, chlamydia, pelvic inflammatory disease, tuberculosis, hepatitis A, acute hepatitis B, and acute hepatitis C. Data are sent to MAVEN utilizing HL7 and PHIN-MS via the ELR infrastructure. ESP is currently deployed at large multi-specialty outpatient provider group that serves approximately 10 percent of the Massachusetts population.

The NEDSS Lead, funded from this Cooperative Agreement, provides technical oversight of the ELR infrastructure. This position works in close collaboration with the HIE Coordinator, funded from the ELC HITECH Agreement, to ensure a sustainable HIE infrastructure to meet the BID's health information exchange needs. During the course of this Cooperative Agreement, it is expected that HIE efforts will increase; ELC funded staff play a critical role in promoting and guiding these efforts to ensure a rapid public health response to infectious disease threats.

b) Operational Plan

Both MAVEN and ELR infrastructure are currently operational, were developed using PHIN guidelines and are fully interoperable. The objectives outlined are in various stages of implementation and sustained funding to support these efforts is critical to their success.

Massachusetts agrees to continue to participate with CDC and its public health partners in NEDSS- related planning and development, to brief key partners in our progress of implementation, and to collaborate with CDC in the planning, design and execution of all phases and aspects of these projects.

Activity 1: NEDSS Personnel Infrastructure

Currently, two FTEs are partially funded on this Cooperative Agreement (split funded with the PHEP Cooperative Agreement). The NEDSS Project Manager and NEDSS Lead will provide ongoing support for the implementation and continued enhancement of MAVEN and ELR. The NEDSS Project Manager will also provide technical oversight of the deployment of MAVEN at LBOHs.

Activity 2: Meeting Program Objectives

- a) Develop, acquire or purchase interoperable public health surveillance systems that adhere to NEDSS and PHIN specifications and requirements

Objective 1: Maintain and enhance MAVEN to ensure surveillance and case management needs of the BID programmatic areas and local boards of health (LBOH) are met.

Staff will:

- Continue to make enhancements and upgrades to MAVEN for use at the state and in LBOHs in a timely manner.
- Upgrade technical infrastructure to ensure MAVEN performance issues are resolved.
- Convert specific functionality within MAVEN to address performance issues.
- Continue to enhance MAVEN for use by the Division of STD Prevention.
- Begin requirements gathering to enhance MAVEN for use by HIV Surveillance.
- Develop plan to assess co-morbidity.
- Begin development of MAVEN evaluation plan.

Year 1 (1/1/12-12/31/12):

- By 3/30/12, MAVEN will be upgraded to be hosted in a clustering environment, thus improving system performance.
- By 6/30/12, the STD module will be fully deployed and the Division of STD Prevention will utilize MAVEN for their surveillance and case management needs.
- By 12/31/12, all appropriate workflows will be converted to improve system performance.

Years 2-5 (1/1/13-12/31/16):

By 6/30/13, document management functionality will be deployed. Plans to conduct comprehensive evaluation of MAVEN will be complete; these will include evaluation of timeliness and completeness of case reports to both BID and to the CDC, and an assessment of

co-morbidity. By 12/31/13, HIV Surveillance will utilize MAVEN. By 12/31/14, comprehensive evaluation of case reports is complete as will a comprehensive evaluation of co-morbidity.

- b) Ensure standards-based electronic exchange of laboratory results (ELR) between clinical laboratories and public health surveillance systems.

Objective 2: Continue implementation of electronic laboratory reporting (ELR) efforts.

Staff will:

- Continue to work with CDC to assess implementation of ELR.
- Continue to facilitate implementation of ELR by national and clinical laboratories.
- Ensure mapping interface is current with preferred LOINC and SNOMEDs.
- Perform quality assurance to ensure data are timely and accurate.
- Implement HL7 2.5.1 messaging between the ELR data store and MAVEN.

Year 1 (1/1/12-12/31/12):

- By 6/30/12, messaging between the ELR data store and MAVEN is converted to HL7 2.5.1.
- By 12/31/12, all clinical laboratories in Massachusetts will report via ELR.
- By 12/31/12, two additional national laboratories report via ELR.
- Quality assurance reports are sent monthly and quarterly.

Years 2-5 (1/1/13-12/31/16):

By 12/31/13, remaining high volume national laboratories report via ELR and quality assurance reports are sent monthly and quarterly.

- c) Ensure standards-based electronic exchange of laboratory results between public health laboratories and public health surveillance systems.

Objective 3: Continue implementation of electronic laboratory reporting (ELR) efforts by Hinton State Laboratory Institute (HSLI).

Staff will:

- Continue to facilitate implementation of ELR by the HSLI as new laboratory information systems (SLIS) are deployed.
- Ensure mapping interface is current with preferred LOINC and SNOMEDs.
- Perform quality assurance to ensure data are timely and accurate.

Year 1 (1/1/12-12/31/12):

- By 3/30/12, reference laboratory sends results via ELR.
- By 12/31/12, viral serology laboratory sends results via ELR.
- Quality assurance reports are sent monthly and quarterly.

Years 2-5 (1/1/13-12/31/16):

Quality assurance reports are sent monthly and quarterly.

- d) Establish standards-based electronic exchange of surveillance data between local health departments and state health departments or between different surveillance systems.

Objective 4: *Continue deployment of MAVEN at local boards of health (LBOH) and ensure data exchange with the City of Boston Surveillance System (BoSS).*

Staff will:

- Continue deployment of MAVEN at the local level.
- Continue to work with the BPHC to ensure appropriate data exchange with MAVEN.

Year 1 (1/1/12-12/31/12):

- By 06/30/12, a road map for data exchange with BoSS is established.
- By 12/31/12, 95% of LBOHs utilize MAVEN.

Years 2-5 (1/1/13-12/31/16):

Will assess barriers to MAVEN deployment at remaining LBOHs, identify additional locally-based surveillance and case management MAVEN enhancements and document business requirements and develop and implement new MAVEN functionality.

- e) Establish standards-based electronic exchange of nationally notifiable disease reports between state health departments and the CDC.

Objective 5: *Utilize PHIN-MS to send nationally notifiable disease reports to CDC.*

Staff will:

- Work with CDC to implement PHIN-MS utilizing the PHIN Case and Public Health Report Message Mapping Guides.
- Utilize legacy methods of messaging until PHIN-MS is certified for all notifiable diseases.
- Work with CDC to certify MAVEN as PHIN compliant.

Year 1 (1/1/12-12/31/12):

- By 12/31/2012, BID will send appropriate notifiable disease conditions via PHIN-MS where mapping guides have been approved.

Year 2-5 (1/1/13- 12/31/16):

By 9/30/13, MAVEN is PHIN certified. Work continues with CDC to update notifiable disease messaging formats to current standards and ensure CDC is notified within appropriate timelines.

- f) Establish standards-based electronic exchange of case report data among public health agencies, state health departments and Health Information Exchanges (HIEs).

Objective 6: *Engage in Department-wide efforts to promote health information exchange.*

Staff will:

- Continue to facilitate and expand the implementation of the *Electronic Support for Public Health (ESP)* initiative, as supported by resources.

- Participate in all appropriate Department and EOHHS working groups to ensure the BIDs needs are promoted.

Year 1 (1/1/12-12/31/12):

- By 12/31/12, Lyme disease and pertussis disease detection algorithms for ESP are validated (resource dependent).
- By 12/31/12, appropriate data elements to be transmitted to BID by HIEs are formalized and new protocols for data exchange with EHRs are developed.

Years 2-5 (1/1/13-12/31/16):

Engagement in HIE efforts continue.

c) Measures of Effectiveness/Measurable Outcomes

Activity 2:

- a) Develop, acquire or purchase interoperable public health surveillance systems that adhere to NEDSS and PHIN specifications and requirements.
 - MAVEN is responsive to surveillance and case management needs of the BID.
 - Surveillance and case management functionality is successfully evaluated and plans to respond to deficiencies are developed.
 - ISIS will provide CDC with the total number of case reports received with a break down of the number received electronically.
 - MAVEN is fully deployed for all notifiable conditions using Interoperable Data Repository.
 - ISIS provides CDC with a report detailing co-morbidity.
- b) Ensure standards-based electronic exchange of laboratory results (ELR) between clinical laboratories and public health surveillance systems.
 - ISIS will provide CDC with all relevant information to assess the implementation of ELR. This will include:
 - Total number of case reports/ time period per condition.
 - Number of case reports/ time period including laboratory information per condition.
 - Number of case reports/ time period receiving Meaningful Use-compatible laboratory data by ELR per condition.
 - Number of case reports/ time period where report was initiated by an ELR of a positive laboratory test per condition.
 - ELR infrastructure meets Meaningful Use requirements.
 - Data received via ELR are complete, timely, and accurate.
- c) Ensure standards based electronic exchange of laboratory results between public health laboratories and public health surveillance systems.
 - HSLI is certified to transmit results within two months of new deployments.
 - Data received via ELR are complete and accurate.

- d) Establish standards-based electronic exchange of surveillance data between local public health departments and state health departments or between different surveillance systems.
 - 95% of LBOHs are utilizing MAVEN.
 - MAVEN is meeting surveillance and case management needs for local public health.
- e) Establish standards-based electronic exchange of nationally notifiable disease reports between state health departments and the CDC.
 - MAVEN is PHIN certified.
 - MAVEN is sending CDC notifiable disease reports according to CDC standards and timelines.

ATTACHMENT 2

FOODBORNE DISEASES

A. Outbreak Surveillance Activities – reporting of outbreaks to CDC

B. OutbreakNet – personnel and training for outbreak detection and response

a) Background, Need and Understanding

Massachusetts is the fourteenth most populous state in the nation, with over six million people distributed over 351 cities/towns. Only five of these cities/towns have populations greater than 100,000, while approximately 270 have populations less than 20,000 (US Census).

Data for Massachusetts show that the five most populous cities or towns and their 2010 Census counts are Boston, 617,594; Worcester, 181,045; Springfield, 153,060; Lowell, 106,519; and Cambridge, 105,162.

The largest county is Middlesex, with a population of 1,503,085. Its population grew by 2.6 percent since 2000. The other counties in the top five include Worcester, with a population of 798,552 (increase of 6.3 percent); Essex, 743,159 (increase of 2.7 percent); Suffolk, 722,023 (increase of 4.7 percent); and Norfolk, 670,850 (increase of 3.2 percent).

Please see below table for a summary of foodborne pathogens for 2010 providing an indication of the disease burden for foodborne illnesses in Massachusetts from bacterial pathogens.

Selected Notifiable	# Confirmed	# of Probable	# of Suspect Cases
Salmonellosis	1263	0	1
Shiga toxin-producing organism	62	16	15
Shigellosis	213	0	2
Campylobacteriosis	1084	0	13
Listeriosis	27	0	2
<i>Vibrio species</i>	53	0	3

Massachusetts local public health operates through 351 individual city and town jurisdictions, with a rapidly diminishing response capacity for public health activities. Most of the 351 cities/towns have part-time boards of health (LBOH) with only approximately two dozen having full time health departments. In about 20% of these jurisdictions, selectmen function as the local public health authority. Maintaining sufficient staffing at LBOHs to carry out all public health functions is a challenge and in many instances and incidents the state health department must provide resources to fill these gaps. Unlike other states with county level infrastructure, Massachusetts must provide coverage to many of the 351 individual jurisdictions on an unpredictable basis. This is why it is so important to retain quality staff in sufficient numbers at the state level.

Proposed Activities

- a) The Massachusetts Department of Public Health (MDPH) requests to add a de-identified module to the Massachusetts Virtual Epidemiologic Network (MAVEN) to capture foodborne illness complaints and incidents. MAVEN allows the direct reporting of notifiable diseases by clinicians and local public health, appropriate data-sharing between state and local public health, and improved data management and analysis. It captures all relevant information on notifiable conditions and data elements are easily added or modified to capture additional information as circumstances change, such as in a pandemic event or an outbreak of foodborne illness. At its core, however, MAVEN is a person-based system that allows multiple disease events to be linked to an individual. MAVEN does have a de-identified functionality to capture critical non-person-based surveillance data, which would include foodborne illness complaints. Currently this information is being tracked by an antiquated legacy access database that is failing. The background work has been done regarding this activity but it cannot progress without the requested funds. This system will radically change how we collect information on foodborne illness complaints, allowing for more complete reporting from our local public health partners in a web-based environment. As all health departments begin using MAVEN, foodborne illness complaint information will be more complete with each passing year.
- b) The MPDH requests continued support for a foodborne/waterborne epidemiologist. This position has resided in the Bureau of Environmental Health, Food Protection Program (FPP) for many years and is invaluable for both the state health department and the LBOHs whom it must support. We have little control over how LBOHs retain and fund sufficient staff for all their public health responsibilities so it is imperative that Massachusetts remain in a position to provide support to the local jurisdictions regarding foodborne and waterborne outbreak response. This is an on-going need for next year and each year after.

Part A: Outbreak Surveillance Activities – reporting of outbreaks to CDC

b) Operational Plan

Activity 1: Demonstrate improved outbreak reporting of foodborne, waterborne, and other enteric pathogens.

To ensure improved outbreak reporting of foodborne, waterborne, and other enteric pathogens, a new module will be developed within MAVEN that will be used by the Working Group on Foodborne Illness Control (WGFIC), which is tasked with foodborne and waterborne response in Massachusetts. This new module, and corresponding question packages, workflows and reports will replace an antiquated legacy access database and track foodborne illness complaints and subsequent environmental investigations. These data will also have the capability to be linked to actual disease and outbreak events within MAVEN.

Year 1 (1/1/12-12/31/1):

- The new module will be developed and deployed.
- All staff responsible for foodborne and waterborne illness investigations will be trained on its use.

- All LBOH that utilize MAVEN will be trained on the use of the new module.

Years 2-5 (1/1/13-12/31/16):

The WGFIC will demonstrate an improved response to reporting through the new module in MAVEN. In July 2011, MDPH promulgated regulations mandating all LBOH utilize MAVEN for their surveillance and case management needs. We expect that the implementation of this will result in more timely reporting of foodborne illness complaints to MDPH resulting in the more timely identification and reporting of foodborne and waterborne outbreaks to our federal partners.

Activity 2: To continue to report foodborne illness outbreaks to CDC using NORS part-time staff specifically dedicated to timely reporting of outbreaks to CDC.

Staff will:

- Report enteric outbreaks via the NORS system to include foodborne illness outbreaks, waterborne outbreaks and person-to-person norovirus outbreaks such as those that occur in institutions such as long term care facilities, hospitals and schools.
- Receive training by trained MDPH staff to use NORS.
- Continue to strive for real time reporting.

Year 1 (1/1/12-12/31/12):

- All outbreak reports will be entered into NORS.
- All data in NORS will be validated and cleaned during the annual close out of data.
- Information collected on outbreaks will include laboratory-confirmed cases, age and sex of cases, number of hospitalizations and number of deaths.

Years 2-5 (1/1/13-12/31/16):

Massachusetts will continue to participate in NORS or any other outbreak reporting systems identified by our federal partners. Massachusetts will strive for complete data for inclusion into these systems for the accurate accounting of outbreaks both within Massachusetts and those that are multi-state in nature. All data will continue to be entered into the system in a timely manner and all data will continue to be validated and cleaned as required.

c. Measures of Effectiveness:

- 1) MAVEN is developed and deployed, and all staff within MDPH are using it to collect information on foodborne and waterborne complaints by 12/31/12.
- 2) At least six outbreaks are reported annually to NORS.
- 3) All Massachusetts outbreak reports are finalized within 60 days of CDC initiation of annual data closeout.
- 4) Proportion of final reports with complete case data in NORS:
 - Number of lab-confirmed cases (100%)
 - Age groups of cases (100%)
 - Sex of cases (100%)
 - Number of hospitalizations (75%)
 - Number of deaths (70%)

Each business day, two epidemiologists are assigned to investigate outbreaks that occur that day. Approximately 15 epidemiologists are trained for this response and assume this responsibility on a rotating basis. The investigating epidemiologist handles all aspects of the investigation from start to completion, including reporting the outbreak to NORS if appropriate.

NORS Statistics for 12-Month period of July 1, 2010 through June 30, 2011

# NORS outbreak reports/1,000,000 persons	% NORS reports with number of laboratory-confirmed cases indicated	% NORS reports with age groups of cases indicated	% NORS reports with sex of cases indicated	% NORS reports with number of hospitalized cases indicated	% NORS reports with number of deaths indicated
1.22/1,000,000	100%	87.5%	75%	87.5%	100%

Eight foodborne outbreaks and 170 unspecified gastrointestinal illness clusters were reported during the above 12 month time period

Part B: OutbreakNet – personnel and training for outbreak detection and response

b) Operational Plan

Activity 1: Improve capacity of state and LBOHs to fully investigate enteric disease outbreaks.

Staff will:

- Continue to investigate foodborne illness complaints and outbreaks, with an emphasis on the coordination of environmental, epidemiologic and laboratory investigations, including retail and manufactured foods.
- Contact LBOH personnel in the 20 largest jurisdictions on a regular basis to ensure all complaints are forwarded to the FPP within 24 hours, until a stable reporting system has been developed (see proposal in *Activity 1* in Part A above).
- Request Hazard Analysis Critical Control Point (HACCP) risk assessments for suspect food items, as well as investigation summary reports.
- Evaluate investigation results received from LBOH for completeness and food-specific detail.
- Include all available environmental data in the Foodborne Illness Database.

Year 1 (1/1/12 – 12-31/12):

- Program staff will provide assistance in foodborne illness investigations, including laboratory-confirmed and epidemiologically linked outbreak investigations.
- During foodborne illness outbreak investigations, all available environmental, epidemiological and laboratory information will be obtained and outbreak reports will be written.

Years 2-5 (1/1/13-12/31/16):

All activities described above will continue in addition to any further activities suggested by federal partners. We expect improved capabilities in LBOH with increasing use of technologies such as wider use of MAVEN and ELR.

Activity 2: Increase and/or enhance state/local health department staff to allow for adequate response to enteric disease outbreaks.

Staff will:

- Provide on-the-job-training and field demonstrations during environmental investigations.
- Assist in the collection of pertinent case information.
- Provide technical assistance by phone as needed.
- Coordinate and participate in field assistance.
- Assist in the proper collection of food and environmental samples.
- Publish guidelines and tools on the website on an ongoing basis as they are developed.
- Develop and update training tools and job aids to use when investigating and tracking suspect FBI outbreaks.
- Continue the local public health internship program which provides master's degree candidate interns to assist LBOHs in public health response during the summer.

Year 1 (1/1/12 – 12-31/12):

- Program staff will provide assistance to local/state health agents for foodborne illness investigations.
- MDPH will recruit interns and health departments to host them from 6/1/12-8/15/12.

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5 MDPH will continue to strive to assist LBOH in their response to foodborne and waterborne diseases and continue to make the case to appropriate entities of the importance of adequate staff in LBOHs. The local public health internship program will continue each summer as it has for the past eight years.

Activity 3: Ensure personnel responding to outbreaks have sufficient training.

Staff will:

- Attend trainings to further enhance knowledge regarding new trends in foodborne and waterborne illness.
- Implement basic training based on the FDA ORA-U curriculum that introduces basic HACCP principles, and risk-based inspection for new food inspectors, and application of these principles for risk-based inspections in routine foodborne illness investigations.
- Develop and implement foodborne illness outbreak investigation training as a component of courses for new food inspectors, as well as a component of additional FPP trainings.

Year 1 (1/1/12 – 12-31/12):

- Staff will attend the CDC sponsored OutbreakNet annual meeting, the Northeast Region Epidemiological Conference, and the Epi Ready Course.
- Foodborne Illness Outbreak Investigation trainings will be developed and given.
- Food safety, inspection and investigation courses are promoted in cooperation with the Massachusetts Environmental Health Association and the Massachusetts Health Officers Association..

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5 we will continue to ensure that all staff within MDPH are fully trained in the latest methods of foodborne and waterborne outbreak investigation. We will continue to extend training to as many LBOH as possible.

Activity 4: Enhance capacity for cross-jurisdictional collaborations, particularly during response to enteric disease outbreaks.

Staff will:

- Develop Standard Operation Procedures (SOPs) for joint inspections with FDA regarding manufactured foods.
- Conduct joint inspections with FDA and LBOHs.
- Participate in multi-state conference calls as they occur.
- Publish, coordinate, and distribute information about foodborne illness and foodborne illness investigations.
- Invite LBOHs to join WGFIC discussions regarding outbreak investigations in their jurisdictions.

Year 1 (1/1/12 – 12-31/12)

- SOPs are developed and joint inspections conducted.
- Information about foodborne illness and foodborne illness investigations are distributed via the HHAN.

Year 2-5 (1/1/13-12/31/16)

Throughout years 2-5 all activities above will continue as resources remain available from either federal or state sources or both. We will continue to invite our local health partners to participate in all outbreak investigations within their jurisdictions.

c) Measures of Effectiveness/Measurable Goals

- 1) MDPH continues to fill positions supported through this cooperative agreement.

Number of staff currently supported:

Tara Harris, Food Protection Program Foodborne Illness Coordinator, 100% of time (37.5 hours a week)

- 2) MDPH continues to ensure that staff are properly trained and participate in trainings that are available either at no cost or low cost as no training resources have historically been available through this cooperative agreement. Any trainings attended are recorded in an on-

going FPP database. Information regarding these trainings will be obtained from this database.

Ms. Harris completed 20 FDA ORA-U Foodborne Illness trainings, and attended an FDA Special Processes Course, from the period from 7/1/10 to 6/30/11.

- 3) MDPH continues to support the attendance at appropriate meetings for personnel supported through this cooperative agreement as there are no resources provided other than time. Meetings attended are also recorded in the FPP database. Information will be obtained from this database in order to track the number of meetings attended in the next year.

Ms. Harris participated in OutbreakNet Quarterly Conference Calls.

Ms. Emily Harvey, Epidemiology Program Foodborne/Waterborne Illness Project Manager attended OutbreakNet in October, 2011 in Long Beach, CA with resources provided directly from CDC.

- 4) The epidemiologist supported in this cooperative agreement along with representatives from the Epidemiology Program and the Bureau of Laboratory Sciences continues to participate in outbreak responses where multi-state collaborations are required. Outbreak investigations are tracked in a shared foodborne illness database and also in an outbreak module in MAVEN. The foodborne illness database collects information on the larger and more complex outbreaks while information regarding all outbreaks and clusters, including all PFGE clusters, are entered into an outbreak module of MAVEN.

From 7/1/10 to 6/30/11 Massachusetts became involved in four large scale multi-state outbreaks and an additional 36 smaller multi-state clusters.

- 5) The WGFIC continues to meet twice monthly to discuss all issues related to foodborne and waterborne illness complaints, to coordinate all outbreak response among epidemiology staff, environmental staff and laboratory staff, to include all appropriate local health department in the discussions and to collaborate with federal partners.

ATTACHMENT 2

FOODBORNE DISEASES

C. OutbreakNet – FoodCORE: Foodborne Disease Centers for Outbreak Response Enhancement

a) Background, Need and Understanding

Foodborne illness imposes a burden on public health and contributes significantly to the cost of health care. As reported in Healthy People 2010, from 1988 through 1992, foodborne illness outbreaks caused an annual average of more than 15,000 reported cases of illness in the US (CDC). The CDC also estimates that each year 31 major pathogens acquired in the US caused 9.4 million episodes of foodborne illness, 55,961 hospitalizations and 1351 deaths (Scallan, et al. *Emerging Infectious Diseases*, Vol. 17, No. 1, January 2011).

Massachusetts, with a population of 6,547,629 (2010), shares the public health burden of foodborne illness. It is estimated that over 200,000 cases of foodborne illness occur each year in Massachusetts. The Massachusetts Department of Public Health (MDPH) realized in 1986 that response to foodborne outbreaks needed a coordinated approach and formed the Working Group on Foodborne Illness Control (WGFIC), an innovative model to oversee foodborne illness response. The WGFIC consists of epidemiologists, laboratorians, food safety specialists, and environmental specialists from the Bureau of Infectious Disease (BID) Epidemiology Program, the Bureau of Laboratory Sciences (BLS), and the Bureau of Environmental Health (BEH), Food Protection Program (FPP).

All foodborne illness complaints are entered into a database and discussed at twice-monthly meetings of the WGFIC. All outbreaks are investigated collaboratively by the WGFIC and facilitated by all members of the group who work at the same location, the William A. Hinton State Laboratory Institute (HSLI) in Boston. In addition to the three MDPH entities that comprise the WGFIC, the local board of health (LBOH) involved in any outbreak under investigation serves as an *ad hoc* member. The Boston Public Health Commission (BPHC), representing the largest single jurisdiction in Massachusetts, is a standing member of the WGFIC and a representative attends all meetings.

Diseases caused by foodborne pathogens are reportable in Massachusetts to the LBOH. The LBOH then reports to MDPH. Laboratory findings, however, for these diseases are reportable directly to MDPH. Reports come to MDPH from LBOHs or labs by fax, phone, mail, or via an electronic laboratory reporting system (ELR). LBOHs are responsible for investigating individual cases of these diseases including completion of case report forms (CRF), which are then returned to MDPH by fax, mail or through the MDPH PHIN-compliant web-based disease surveillance and case management system (MAVEN). The time from positive results to a completed interview can range from days to weeks; in some cases, depending on the resources of the LBOH, the investigation may not be completed at all. MDPH now requires the submission of selected isolates and diagnostic specimens to the BLS for further testing. These include *Listeria* and *Salmonella* isolates, Shiga toxin-producing organism isolates, and any broths that test

positive for Shiga toxin-producing organisms where the organism has not been isolated. This allows for more rapid PFGE testing of isolates and a more timely recognition of outbreaks.

In addition to the WGFIC, the development and deployment of MAVEN in Massachusetts enables MDPH and LBOHs to share and transfer appropriate public health, lab, and clinical data efficiently and securely over the Internet according to national standards. MAVEN is configurable for disease investigation, form development, survey design, and data collection. Specifically, the application allows for direct reporting of diseases by clinicians and LBOHs, appropriate data-sharing between MDPH and LBOHs, direct access to data by epidemiologists and nurses, and improved data management and analysis. MAVEN captures all relevant information on notifiable conditions and is easily modified to capture additional information such as findings from environmental assessments during an outbreak. As a web-based application, MAVEN is accessible from any location that has Internet access and fully integrated with MDPH's ELR efforts. Modifications to MAVEN will allow for capture of the information generated by this project and increase access to that information to key partners.

Capacity in Massachusetts to conduct foodborne illness investigations is provided through a variety of funding mechanisms including the ELC Cooperative Agreement, the FDA Rapid Response Team (RRT), the FDA Food Emergency Response Laboratory Network (FERN), and state funding.

In 2010 alone nearly 1,500 cases of *Salmonella*, *Listeria* and STEC were reported to MDPH. While the WGFIC is in place and MAVEN and ELR are both providing the infrastructure for timely reporting and response, the WGFIC must still rely on the LBOH to interview cases of foodborne illness. This reliance hampers efforts for the timely identification of outbreaks and subsequent response. In Massachusetts, public health operates through 351 cities and towns, each its own jurisdiction. Only five of these cities/towns have populations greater than 100,000. Most of the 351 cities/towns have part-time boards of health with very few full time health departments. In about 20% of these jurisdictions, selectmen function as the local public health authority. MDPH does not have the resources to assume the LBOH role in foodborne illness investigations or to perform all environmental assessments or necessary testing in real time, e.g. *Salmonella* serotyping, parasitology testing, or norovirus testing.

Massachusetts requests consideration to become a FoodCore Disease Center for Outbreak Response Enhancement. This will allow Massachusetts to respond to foodborne illness in their state in a more centralized fashion. Massachusetts will participate in all the activities outlined in the core areas. The WGFIC as a group and the individual entities within have worked collaboratively for 25 years with all the LBOHs within the state, other state health departments, other state agencies, and federal partners such as FDA, CDC, USDA, and FSIS. The WGFIC has close working relationships with the MA Medical Society, the MA Veterinary Medical Association, the Northeast state health departments, and the Council of State and Territorial Epidemiologists.

While the capacity and expertise of the WGFIC is extensive, additional resources will be required to successfully implement this program and will include a Bacteriologist I & II, an

Epidemiologist II, a Food and Drug Inspector III, and four part-time interns. All positions will be hired in accordance with state requirements regarding required experience and qualifications for these positions. The Epidemiology Program will build on established relationships with local schools of public health and health professions to recruit student interns for this project. When in place, the new staff along with in-kind staff will accomplish all program goals including providing assistance to all LBOHs and outreach to other states as necessary and appropriate.

b) Operational Plan

Activity 1: Enhancement of public health laboratory surveillance

Laboratory staff will:

- a) Ensure routine transportation of bacterial, viral or parasitic specimens from clinical laboratories to the HSLI by identifying roadblocks that slow down or prevent the timely submission of specimens. The Bureau of Laboratory Sciences (BLS) will assess shipment of specimens from those clinical labs who use US mail or courier and have frequent prolonged specimen transit times to identify delays specific to the institution and provide advice for improvement. A gap analysis will be performed by: a) comparing the numbers of enteric specimens submitted to the HSLI and cases of enteric disease reported in MAVEN; b) determining the time between identification of an enteric pathogen at the clinical lab and receipt of the isolate/specimen at the HSLI; and, c) determining the mechanisms by which specimens are transported to the HSLI for each laboratory. Resources will be identified and provided to address problems and gaps.
- b) Conduct real-time serotyping and PFGE subtyping of all strains of *Salmonella*, Shiga toxin producing *E. coli* (STEC) and *Listeria* completed within four working days of receipt at the HSLI. Due to decreased resources, conventional serotyping of enteric pathogens has often lagged behind PFGE in terms of turnaround time. The BLS currently conducts PFGE subtyping of all isolates in real time using BioNumerics version 5.1. All isolate patterns are uploaded within 24 hours of fingerprint pattern generation, and compared to every other isolate in our database in the same time frame. Ninety percent of all STEC, *Listeria* and *Salmonella* PFGE patterns are uploaded to PulseNet within four days of isolate submission.
- c) Use PulseNet to link by subtype and PFGE any pathogens identified from testing the implicated or suspect products to persons infected with the same strain of bacteria. All groups within the WGFIC share cluster and outbreak information in real-time, facilitating prompt collection and submission of suspect food commodities for testing.
- d) Ensure transport of specimens from outbreak victims to the HSLI under conditions of uncertain diagnosis via MDPH funded couriers as needed. They will work with LBOHs to distribute specimen collection “kits” to outbreak cases and facilitate specimen submission by MDPH funded courier.
- e) Provide transport of Shiga toxin positive broths to the HSLI for real time isolation and subtyping of STEC via couriers as needed.
- f) Explore software links to permit rapid sharing of PulseNet information with epidemiologists to facilitate interview and investigation. Currently relevant information is shared among all WGFIC members in person or by phone in real time. They work

- together to ensure prompt collection and submission of suspect foods to the HSLI, perform PFGE on food and clinical isolates in real time, and upload PFGE patterns to PulseNet as completed
- g) Conduct real-time video microscopy for submission to DPDx. This capability will be re-established with resources provided.
 - h) The BLS staff is currently in the process of re-establishing their calicivirus testing capability with resources provided through ELC-ACA. With this additional funding BLS staff will characterize calicivirus strains that are linked to foodborne illness outbreaks and submit this data to CaliciNet. BLS has a robust molecular diagnostics program with extensive experience with validating, implementing, and performing conventional and real-time PCR. BLS staff can ensure unidirectional workflow for molecular testing, and is fully equipped to perform high-throughput PCR and nucleic acid sequencing.
 - i) Collect serologic samples from persons with hepatitis A virus infection linked to foodborne disease outbreaks to further molecular characterization.
 - j) Send all results from the BLS laboratory information system (IML) electronically to MAVEN. Both BLS and ISIS will enhance both IML and MAVEN systems to maintain the current method of sharing PulseNet information with epidemiology offices and to improve it

Activity 2: Epidemiological interviews and investigations

Much of the follow up for individual cases is the responsibility of the LBOHs which use existing case report forms (CRF) to collect minimal demographic, clinical, and risk information. For laboratory results sent to MDPH, notifications are sent to the LBOH of the case's residence as soon as the report is entered into MAVEN. The notification and subsequent interview process is not dependent on the results of serotyping or PFGE. The additional resources provided with this funding will allow MDPH to provide an immediate response to identified cases at the state level and allow for full participation in these activities for the full 12 months of the budget period. Recruitment of interns and proposed staff will begin as soon as notice of grant award is received.

Epidemiology staff will:

- a) Conduct centralized rapid interviews to collect demographic, clinical, risk factor, and other information using a standard form for all diagnosed cases of infections *Salmonella*, STEC, and *Listeria*, as soon as the case is identified. All cases of *Salmonella*, STEC, and *Listeria* are designated as "immediate" in MAVEN, prompting an alert to an epidemiologist who will assign the case to a student intern. Boston resident cases will be assigned to an intern physically located at the BPHC, who will handle the response. For all other cases LBOHs that prefer to administer the questionnaire will be given 48 hours to do so. If unsuccessful, the student intern will resume responsibility for the case. Student interns will complete these interviews as quickly as possible, attempting to contact the cases on evenings and weekends in addition to usual work hours.
- b) Collaborate with CDC and all awardees to develop and implement standard core questionnaires for initial screening and hypothesis generation for all diagnosed cases of infection with *Salmonella*, STEC, and *Listeria*,

- c) Conduct real-time review of subtyping results of *Salmonella*, STEC, and *Listeria*, so that interviews of possible cluster-associated cases are evaluated together.
- d) Conduct additional follow-up investigations that are prompted by detection of a cluster or local outbreak, including participating fully in large multi-state outbreak investigations, and in assessment of cases with patterns matching isolates from foods. The WGFIC has extensive experience in both local and multi-state outbreak investigations and also has been involved in assessment of cases with patterns matching isolates from food. As the PFGE and enteric laboratory are located in the same building as the Epidemiology Program, PFGE clusters are communicated directly to epidemiologists either in person, by phone, or through email as soon as they are noted. Additional interviews will be conducted as necessary using more specific tools
- e) Collect information from well persons as part of analytic epidemiologic studies for multi-state foodborne outbreak investigations. Student interns will collect information on controls, in a timely manner, including evenings and weekends.
- f) Obtain product information from persons infected with a strain of bacteria that matches by PFGE a strain identified in a product. This information will be passed on to the FPP program for additional follow up to locate and obtain any product still available.
- g) Complete a NORS report for every outbreak of foodborne enteric disease identified in applicable jurisdictions.
- h) Participate in team training of LBOH staff in methods of outbreak investigations.

Activity 3: Environmental health activities

Food Protection Program staff will:

- a) Complete the food-specific portions of the NORS form containing additional information relating to the specific type of implicated food product or ingredient and method of preparation for outbreaks of foodborne enteric disease outbreaks.
- b) Conduct local environmental assessments during clusters, outbreaks, and complaints; gather information for tracing food sources as part of the WGFIC investigative team.
- c) Obtain implicated and suspect products for laboratory testing, as well as information such as sell by dates and lot numbers related to these products. Food and environmental surveillance sampling protocols will be completed within 18 months; particular attention will be paid to food products shipped interstate with the potential to cause multi-state outbreaks.
- d) Provide, as part of the team, training of local health inspectors in methods of basic outbreak investigations. This will include educational opportunities for local health investigators on foodborne illness and foodborne illness investigations, including environmental assessments, sampling protocols, food recalls, field inspections, and related procedures. FPP will evaluate current local health training plans and develop new training specific to the environmental health role as needed.

Activity 4: Laboratory, Epidemiology and/or Food Protection Program staff will attend the Annual OutbreakNet Conference and the FoodCore Vision Meeting.

Year 1 (1/1/12 – 12-31/12):

All activities will be in place by the end of Year 1.

Years 2-5 (1/1/13-12/31/16):

All activities will remain in place for the subsequent four years of the cooperative agreement. Additional activities will be added based on the needs of federal partners and the collective decisions of the Foodborne Disease Centers.

c) Measures of Effectiveness/Measurable Goals

Measures of Effectiveness:

- Serotyping and PFGE subtyping of all strains of *Salmonella*, *Listeria* and STEC is completed within four working days of the availability of the isolates at the BLS.
- For samples that come directly to the HSLI, the time from sample collection to the availability of PFGE results will approximate <10 days for food samples and <5 days for human samples. Time from sample collection to PFGE results on human samples sent to private clinical laboratories first will approximate <10 days. Time from the identification of *Salmonella*, STEC, and *Listeria* in the clinical lab setting to PFGE results will be <7 days.
- All reported cases of *Salmonella*, STEC, and *Listeria* are designated as “immediate” in MAVEN. Epidemiologists are alerted, cases are assigned to an intern and the interview process is initiated.
- 90% of *Salmonella*, STEC, and *Listeria* cases have some level of demographic, clinical and exposure information collected within three days of when the report is entered into MAVEN. Criteria for “completeness” is developed.
- 100% of *Salmonella*, STEC, and *Listeria* clusters are investigated.
- The median time to initiate investigations of foodborne illness clusters is three days.
- The proportion of *Salmonella*, STEC, and *Listeria* clusters where implicated or suspect food product is collected for laboratory testing increases during the first year of the project period compared to the prior year.
- The proportion of *Salmonella*, STEC, and *Listeria* clusters where a source of illness is identified increases during the first year of the project period compared to the prior year.
- All *Salmonella*, STEC, and *Listeria* clusters where a source has been identified are evaluated as to the appropriateness of providing a public health message to the public.
- All *Salmonella*, STEC, and *Listeria* clusters are evaluated as to the appropriateness of enacting a recall or regulatory action.
- A NORS form is submitted on all *Salmonella*, STEC, and *Listeria* outbreaks.
- Environmental investigations are conducted when a FBI outbreak is linked to a restaurant or food service establishment 100% of the time.
- The WGFIC analyzes and evaluates all food samples from products shipped interstate with the potential to cause widespread, multi-state outbreaks.

Measurable Goals:

The following indicators are for the time period 1/1/2011-6/30/2011. These indicators with any additional indicators will be provided for all project years.

- 1) Total number of *Salmonella*, STEC, and *Listeria* (SSL) isolates and isolate-yielding specimens.
Result: 523
- 2) Time from receipt of SSL isolate-yielding specimens at PHL to recovery of isolate.
Result: *Salmonella* and STEC range, 2-11 days/average=5 days
Listeria range 3-8 days/average=4 days
- 3) Percent of *Salmonella* primary isolates with complete serotype information and % of STEC primary isolates with serotype information (N/A for *Listeria* isolates).
Result: *Salmonella*= 441/477 92.4%, STEC=19/39 48.7% (all non-O157 isolates are sent to CDC for confirmation)
- 4) Time from SSL isolate receipt (or recovery) at PHL to serotype result.
Result: *Salmonella* range 2-62 days/average=4 days
STEC range 2-171 days/average=36 days, median=6 days, mode=5 days
- 5) Percent of SSL primary isolates with PFGE information.
Result: *Salmonella* = 86%,
STEC = 100%
Listeria = 100%
- 6) Time from SSL isolate receipt (or recovery) at PHL to PFGE upload to PulseNet.
Result: *Salmonella* = 2.5 days
STEC = 3.5 days
Listeria = 3.56 days
- 7) Number of laboratory confirmed SSL cases reported to epidemiology staff.
Result: *Salmonella* = 425
STEC = 19
Listeria = 9
- 8) Percent of SSL cases with attempted interview.
Result: A total of 391 out of 453 cases (86.31%) were investigated by local boards of health.
- 9) Percent of SSL cases with complete food history obtained.

Result: Of the 453 cases that submitted specimens as stated above, a food history was obtained for 190 cases (41.94%). Per Jennifer Wright at the CDC, a complete food history is defined as the following:

Complete food history: To include an interview (of any format) which assesses foods consumed prior to onset of illness, or determines food preference, via an open-ended food history, or via a list of potential foods. The key factor to be considered a complete food history is an interview that goes beyond assessment of high-risk settings and prevention education to ascertain food consumption.

Food history completeness was assessed using the MAVEN question "Suspect food or drink" which is an open text field. If this answer was not left blank, it was considered to be a complete food history. If this question was answered with "unknown" or "not sure" it was still considered to be a complete food history since the case was asked to some extent if they could recall what food could have caused their illness.

10) Percent of SSL cases with PFGE where complete epidemiologic data is collected.

Result: Complete demographic data: To include State, County, Birth Month, Birth Year, Sex, Race, Ethnicity
Complete epidemiologic data: To include complete demographic data as well as a complete food history

38.85% of all 453 cases had race information collected (this includes where race was completed as "Unknown"). 57.62% of all 453 cases had ethnicity information collected (using the question "Hispanic?"). Taken together, a total of 144 cases or 31.79% of the 453 cases had complete demographic data.

Taking into account whether cases that had complete demographic data also had complete food histories, a total of 85 cases or 18.76% of cases were considered to have complete epidemiologic data.

11) Percent of SSL clusters with routine interview of cases.

Result: 100% of the cases had routine interviews.

12) Percent of *Salmonella* and STEC clusters with >10 cases and *Listeria* clusters with >5 cases where an analytic epidemiologic study (statistical comparison against a control group or within a cohort) was conducted.

Result: We did not have any clusters during this time period that met the number of cases criteria.

13) Percent of SSL clusters with suspect vehicle/source identified.

Result: 33% (5/15)

14) Percent of SSL clusters with confirmed vehicle/source identified.

Result: 26.6% (4/15)

15) Percent of SSL clusters with identified vehicle/source where public health action was taken.

Result: 13.3% (2/25)

16) Percent of SSL clusters with link to a restaurant/food establishment where an environmental health assessment was conducted.

Result: 16%

17) Percent of SSL clusters where food or environmental sample collected for testing.

Result: None

18) Percent of outbreaks where National Outbreak Reporting System (NORS) form completed.

Result: 6.7% (1/15)

ATTACHMENT 2

FOODBORNE DISEASES

D. PulseNet

a) Background, Need and Understanding

Massachusetts is the fourteenth most populous state in the nation, with over six million people distributed over 351 cities/towns. Only five of these cities/towns have populations greater than 100,000, while approximately 270 have populations less than 20,000 (US Census).

Data for Massachusetts show that the five most populous cities or towns and their 2010 Census counts are Boston, 617,594; Worcester, 181,045; Springfield, 153,060; Lowell, 106,519; and Cambridge, 105,162.

The largest county is Middlesex, with a population of 1,503,085. Its population grew by 2.6 percent since 2000. The other counties in the top five include Worcester, with a population of 798,552 (increase of 6.3 percent); Essex, 743,159 (increase of 2.7 percent); Suffolk, 722,023 (increase of 4.7 percent); and Norfolk, 670,850 (increase of 3.2 percent).

Massachusetts Disease burden

Please see below table for a summary of foodborne pathogens for 2010

Selected Notifiable	# Confirmed	# of Probable	# of Suspect Cases
Salmonellosis	1263	0	1
Shiga toxin-producing org.	62	16	15
Shigellosis	213	0	2
Campylobacteriosis	1084	0	13
Listeriosis	27	0	2
<i>Vibrio species</i>	53	0	3

Massachusetts has been an active PulseNet lab and an area lab since 1996. From the inception of PulseNet, Massachusetts has been a leader in contributing to the robustness of the national database, identifying local and national outbreaks, and testing new methodologies. From 7/1/10 to 6/30/11, Massachusetts's local laboratories reported 1,168 confirmed cases of *Salmonella*, 182 confirmed cases of *Shigella*, 58 confirmed cases of STEC (*E. coli* O157 and non-O157), and 21 confirmed cases of *Listeria monocytogenes*. Since 2007, Massachusetts public health regulations have mandated that each case be reported to the Massachusetts Hinton State Laboratory Institute (HSLI), and that the isolate be forwarded to the HSLI for confirmation and additional tests such as serotyping and PFGE, and surveillance. Each isolate is confirmed in the laboratory in accordance with current protocols, serotyped using the Kauffman-White Scheme for identification of *Salmonella* serovars, and subtyped as a part of the CDC PulseNet program. All isolates are uploaded to the national PulseNet database for comparison to other isolates nationally. Massachusetts has six operational CHEF Mapper XA units. Gels are run five days a week, allowing a total of 66 isolates to be run, analyzed and uploaded each day.

The Massachusetts Bureau of Laboratory Science (BLS) is currently the Area PulseNet Laboratory for the Northeast Region. During the past year we assisted in the routine PFGE of *L. monocytogenes* for Maine and Rhode Island, and also maintained capacity in the form of surge testing when necessary, and supplies such as enzymes if they were depleted.

The Northeast region as a whole has had little turnover and has a high number of well trained, long-term PFGE analysts. As such, other states' reliance on Massachusetts is limited to specific surge events during outbreaks and coverage for staffing issues if any arise. However, in 2007, the Northeast region began accepting a number of regional surveillance projects and convened the Northeast Regional Working Group to develop and maintain these surveillance projects. The Northeast region, under the guidance of Massachusetts, has emerged as a leader in the concept of regional surveillance. Given that the Northeast region is geographically small, a small cluster of illness could be first seen with one isolate in each of several states. The regional perspective is an important bridge between local and national surveillance.

Massachusetts is well situated to participate in programmatic and outbreak response activities that span several agencies. The BLS is co-located with the Bureau of Infectious Disease (BID) and the Food Protection Program (FPP) at the HSLI; together these three components of MDPH form the Working Group on Foodborne Illness Control (WGFIC). The group meets at least twice monthly to discuss active investigations of outbreaks of foodborne illness, and clusters of illness related by matching PFGE patterns. Shared network databases allow information to be transferred and shared among all members of WGFIC. Massachusetts BLS infrastructure enables our internal LIMS system to communicate directly with the epidemiologists data management system (MAVEN), and with local hospital laboratories via electronic laboratory reporting (ELR). As a result, critical information such as test results and reports are transferred in near-real time, every 30 minutes, from the lab to ELR and MAVEN.

Massachusetts has had a number of successful outbreak investigations. In 2011, we saw an increase in *Salmonella* Thompson cases with matching PFGE patterns. This information was rapidly transmitted to the Epidemiology Program and FPP through the use of our shared network folders. The epidemiologists were able to quickly locate the initial case report forms completed by the local health agents in the towns where the cases resided. We soon determined a number of the cases ate at a popular ice cream stand and restaurant in a particular county. FPP staff members, along with local health inspectors then inspected the restaurant and ice cream parlor to determine if the food was safe for the public. It was noted that one of the cases was an employee of the ice cream parlor. This identification led the WGFIC to require stool samples of the ice cream scoopers and grill cooks. A second employee was identified as positive for *Salmonella* (although a different serotype) and suggestions were made to the owners regarding barrier protection and exclusion from work for employees with or suspected of having (based on symptoms) *Salmonella* infections. Through the diligence of real-time PFGE analysis, and the quick teamwork of the members of WGFIC, we were able to reduce the burden of illness to potentially a large number of people.

Also in 2010-2011, an EID fellow working at MPDH created a library of PFGE patterns of *Salmonella* and *Campylobacter* isolated from raw whole chickens purchased from Massachusetts

markets. This project involved testing nine raw chickens over a nine month period, and resulted in 18 different unique *Salmonella* PFGE patterns (of seven different serotypes) and 29 different unique *Campylobacter* PFGE patterns being added to our local database. It also resulted in one local market being investigated by FPP staff. The overall findings were presented in a poster at the IAFP conference in July of 2011, and a manuscript is currently being prepared for publication.

MDPH requests funding to continue participation in the PulseNet program. We consistently strive for all isolates of all organisms be uploaded within four days. Currently, greater than 89% of all isolates of *Salmonella*, *Shigella*, and STEC are uploaded in that time. During 2012 we expect to increase that overall percentage to 93%. MDPH requests funding to continue exploration of next generation subtyping methods as well. One analyst will be certified in MLVA by the end of 2011, and during 2012 would like to perform testing on organisms requested by CDC for outbreaks or novel strains from within Massachusetts and neighboring states. In addition, a second analyst will be certified for all available organisms by June 2012. As new technologies become available, MDPH will volunteer to assist in validations.

Massachusetts has been conducting an internal validation of the Luminex platform for *Salmonella* serotyping. For the past few years we have been running some isolates in parallel on the Luminex and using the traditional techniques. In the upcoming year, we anticipate completing the full validation, and in subsequent budget years to transition to the Luminex for all routine isolates, saving the traditional methodologies for the more difficult serotypes.

Additionally, we expect to continue to fulfill our requirements as an area laboratory. We will continue to offer to train analysts on PulseNet certified protocols in laboratory methods, analysis, and data management either in Massachusetts, or in the requesting state lab. Massachusetts will continue to offer assistance in surge capacity during outbreaks, staffing shortages, and media and reagent shortages. We will continue to offer to run *Listeria* PFGE testing for Maine and Rhode Island, and any organism from any state that is unable to do so for any reason. Massachusetts will offer to participate in external validations of procedures and software updates as requested by CDC. We will provide expertise when requested through surveys or serving on committees, such as the current web portal working group, and upcoming committees such as the non-culture based methods committee. Massachusetts will continue to serve on the agenda planning committee for the Annual Update Meetings, and would offer to host a meeting in the future. Massachusetts will continue to take a leadership role in implementing regional PulseNet activities including regional surveillance efforts established in 2007 and new initiatives that arise. Funding is requested to support both a Northeast regional update meeting and a Northeast Regional Working Group meeting (NERWG) in 2012.

Massachusetts holds a seat on the PulseNet Steering Committee, and is very active in discussions and planning sessions and setting policy for the program as a whole. Massachusetts represents the entire Northeast region as well as Massachusetts on the steering committee and takes pride in illustrating the state perspective and the regional perspective in all steering committee discussions.

b) Operational Plan

Activity 1: *Coordinate with local laboratories to submit isolates for surveillance, and to upload PFGE patterns to the national database within four days of receipt in the PFGE Laboratory.*

Year 1 (1/1/12-12/31/12) staff will:

- Provide mail-out/mail-in specimen collection kits to assist in obtaining specimens.
- Provide courier delivery system to transport clinical specimens from patients to the local board of health (LBOH) and from the LBOH to HSLI when needed.
- Educate LBOH regarding the appropriate collection of specimens, and to provide specimen collection material.
- Determine the need for engaging couriers to facilitate submission of isolates from hospitals to HSLI.
- Coordinate with epidemiologists to confirm that the laboratory receives isolates for all reported cases.
- Ensure all isolates are uploaded to the national database within four days of receipt in PFGE.

Years 2-5 (1/1/13-12/31/16):

All activities will continue in years 2-5 with expected improvements in performance.

Activity 2: *Continue to perform PulseNet activities.*

Year 1 (1/1/12-12/31/12) staff will:

- Participate in PulseNet, with reporting of results to CDC as requested.
- Perform PFGE on all *Salmonella*, *E. coli* O157:H7, non-O157 STEC, *L. monocytogenes*, *Campylobacter*, *Vibrio parahaemolyticus*, and *Shigella* isolates.
- Use communication protocols to communicate clusters to the Epidemiology Program.
- Post clusters to the CDC Team in a timely fashion.
- Monitor CDC Team Forum activity and respond to new postings within 48 hrs.
- Attend the annual PulseNet meeting.

Years 2-5 (1/1/13-12/31/16):

All activities will continue in years 2-5 with expected improvements in performance.

Activity 3: *Development of next generation subtyping technologies*

Year 1 (1/1/12-12/31/12):

- Two analysts will complete initial certification for all current existing MLVA protocols
- Analysts will participate in development and validation of new technologies as requested by CDC
- Isolates will be serotyped routinely using the Luminex methodology when the validation of the Luminex platform for molecular *Salmonella* serotyping is completed.

Years 2-5 (1/1/13-12/31/16):

All activities will continue in years 2-5 with expected improvements in performance.

Activity 4: Continue to perform the expanded responsibilities of a PulseNet Area Lab.

Year 1 (1/1/12-12/31/12) staff will:

- Train PulseNet laboratorians from other states as requested.
- Provide phone or on-site consultation to other state laboratories in area as requested.
- Process and analyze isolates received from other state laboratories in area as requested.
- Provide assistance with second enzyme testing to laboratories in the Northeast region as requested.
- Participate in additional projects and validations with CDC as needed.
- Participate in all Area Lab conference calls coordinated by the CDC and APHL.
- Attend the annual PulseNet meeting.
- Coordinate biannual conference calls among all Northeast Regional states.
- Initiate planning for 4th Northeast Regional PulseNet meeting, to be held in 2012.
- Continue to coordinate development and implementation of regional projects discussed during the 2007 and 2010 Regional PulseNet meetings.
- Continue to lead Northeast Regional working group activities.
- Coordinate a Northeast Regional Working Group in-person meeting to be held in 2012.

Years 2-5 (1/1/13-12/31/16):

All activities will continue in years 2-5 with expected improvements in performance.

Participation in additional projects and validations with CDC will continue to occur as identified.

c) Measures of Effectiveness/Measurable Goals

Measures of Effectiveness

Activity 1:

- At least 95% of reported cases of *Salmonella*, *Shigella*, and STEC has an accompanying isolate submitted to the HSLI. For the period 7/1/10 to 6/30/11, 94% of all reported cases had an isolate submitted for PFGE.
- At least 95% of *Salmonella* isolates are uploaded to the Pulsenet National Database within four days. For the period 7/1/10 to 6/30/11, 94% were uploaded to the Pulsenet National Database within four days.
- A baseline of the time an isolate is received at HSLI from the time of collection of the specimen and the time of isolation in the local clinical laboratory is developed.

Activity 2:

- *E. coli* O157:H7, non-O157 STEC, and *L. monocytogenes* are tested by PFGE and uploaded to the CDC National database within 96 hours of receipt in the HSLI PFGE Laboratory.
- All *Salmonella* and *Shigella* isolates submitted for PFGE testing are run and uploaded to the CDC National database within one week of receipt in the HSLI PFGE Laboratory.
- Cluster and outbreak information is communicated to epidemiologists in a timely manner.
- Lab staff scores >85% in annual competency exams specific for the PFGE Laboratory.
- The annual PulseNet meeting is attended by one PulseNet laboratorian.

Activity 3:

- Two analysts are certified by CDC for MLVA of *Salmonella* Enteritidis, *Salmonella* Typhimurium, *Listeria monocytogenes*, and *E. coli* O157:H7 by 06/30/2012.
- MLVA is completed on outbreak isolates and other isolates of interest from Massachusetts as requested by CDC.
- PFGE Analysts participate in validations of new technologies as they become available from CDC.

Activity 4:

- High-priority isolates from regional laboratories are analyzed within three business days.
- At least 75% of low-priority isolates from regional laboratories are analyzed within five business days.
- Requests for technical assistance are responded to within 24 hours of receipt of request.
- Requests for training are met within one month from receipt of request.
- The annual PulseNet meeting is attended by at least one senior PFGE staff member.
- Steering Committee calls and in person meetings are attended.
- Area Lab conference calls and in person meetings are attended.
- Northeast Regional conference calls are coordinated at least twice each year.
- A Northeast regional meeting is coordinated and held in 2012.
- Participation in additional projects and validations with CDC occur as needed.

Measurable Goals

Please refer to Activity 1 regarding our plans to enhance and encourage the collection of clinical specimens from LBOHs and clinical facilities to the HSLI. In outbreak situations there will be specific coordination with both the Epidemiologists and the FPP regarding facilitated transport.

The MDPH PFGE Laboratory currently has four FTEs devoted to PFGE. At least one analyst is fully certified in each PulseNet organism. Each analyst maintains annual competency for each organism they are certified for. Refer to the following table for a breakdown of current trained analysts.

PulseNet Personnel	New/ Continuing	If New, Start Date	% Time on PFGE/PFGE Analysis (est.)
Ex: John Smith	New	10/23/2010	50%
Lawrence Connolly	Continuing		100%
Janis Parrin	New	11/01/2010	85%
Tudor Chiorean	New	02/14/2010	75%
Brandon Sabina	New	07/06/2010	100%

From 7/1/10 to 6/30/11, Massachusetts ran close to 800 gels.

(07/01/2010 through 06/30/2011)					
	Total # of isolates received during past 12 months*	Total # of isolates run by PFGE during past 12 months*	How many isolates were run with primary enzyme?	How many isolates were run with secondary enzyme?	How many isolates were run using next generation typing methods?
<i>E. coli</i> O157:H7	56	46	32	32	0
Non-O157:H7 STEC	31	23	12	12	0
<i>Listeria</i>	21	22	22	22	0
<i>Salmonella</i>	1339	1264	1264	265	0
<i>Shigella</i>	176	176	176	0	0
<i>Campylobacter</i>	104	85	85	4	0
<i>Vibrio cholerae</i>	3	0	0	0	0
<i>Vibrio parahaemolyticus</i>	18	16	16	11	0

Area Lab Responsibility	Area Lab Notes
Training of personnel in area labs: include number of people trained, dates, subject matter	No requests for training were made during the specified time period.
Travel to labs within area: travel for training, troubleshooting, etc.	No travel to any labs was requested.
Surge Capacity: list number of isolates rec'd from each state for PFGE; include supplies sent to states	Massachusetts sent supplies to NJ while they were running short. We routinely perform PFGE on <i>Listeria</i> for Maine and Rhode Island. A total of 5 were run during this time period. During outbreaks Massachusetts offers to assist in surge capacity testing or to send enzymes and other reagents as needed to other states in our region.

ATTACHMENT 2

FOODBORNE DISEASES

E. PulseNet – Surveillance for Shiga toxin-producing *E. coli*

a) Background, Need and Understanding

Massachusetts is the fourteenth most populous state in the nation, with over six million people distributed over 351 cities/towns. Only five of these cities/towns have populations greater than 100,000, while approximately 270 have populations less than 20,000 (US Census).

Data for Massachusetts show that the five most populous cities or towns and their 2010 Census counts are Boston, 617,594; Worcester, 181,045; Springfield, 153,060; Lowell, 106,519; and Cambridge, 105,162.

The largest county is Middlesex, with a population of 1,503,085. Its population grew by 2.6 percent since 2000. The other counties in the top five include Worcester, with a population of 798,552 (increase of 6.3 percent); Essex, 743,159 (increase of 2.7 percent); Suffolk, 722,023 (increase of 4.7 percent); and Norfolk, 670,850 (increase of 3.2 percent).

Disease burden

Please see below table for a subset of notifiable, communicable diseases for 2010

Selected Notifiable	# Confirmed	# of Probable	# of Suspect Cases
Shiga toxin-producing organism	62	16	15

Infection caused by Shiga toxin-producing *E. coli* (STEC), O157:H7 and other non-O157 strains, is a growing problem in the US. From 7/1/10 to 6/30/11, in Massachusetts, 65% of all infections caused by STEC were from strains other than O157:H7. In 2009, APHL published guidance for hospital and clinical laboratories on routinely culturing for the top six most common STEC strains. Even with the new guidelines, many labs are not routinely culturing for anything other than O157:H7. And even when they are, STEC are not easily identified by traditional cultural methods. In addition, there are widely used non-culture based methods for the detection of Shiga toxin in stool which means the isolate is not always available for identification, serotyping, and PulseNet surveillance.

Massachusetts public health regulations mandate that all cases of illness caused by *E. coli* O157:H7 or any non-O157 Shiga toxin positive organism be reported to the Massachusetts Department of Public Health (MDPH) Office of Integrated Surveillance and Informatics Services (ISIS) and any isolate, or stool or broth suspected to contain an STEC be forwarded to the Hinton State Laboratory Institute (HSLI) for confirmation, identification, and PFGE subtyping.

Following the *E. coli* O104:H4 outbreak in Germany earlier this year, the Microbiology Division at the HSLI sent a clinical advisory to all clinical laboratories in Massachusetts requesting that Shiga toxin tests (such as EIA or lateral flow type assays) be run on stool specimens from

patients with travel history to Europe. If that test could not be performed at the local laboratory, submission of the specimen was requested to HSLI. In 2012 Massachusetts will duplicate that memo for an increased population of people in an attempt to capture the true burden of illness caused by STEC. In subsequent years, we will increase the subsets of populations targeted for routine Shiga toxin testing. HSLI will work with the local clinical laboratories to offer updated testing methodology. The HSLI will enhance its capacity for STEC detection and identification. Currently, all isolates and stool specimens are tested using the Meridian Premier EHEC EIA. In 2012, Massachusetts will begin the process of instituting a PCR based technology for Shiga toxin detection. Additionally we will continue to validate and use immunomagnetic separation (IMS) as an enhancement to culture or PCR. In 2010-2011, Massachusetts received funding to validate IMS technology for the top six STEC serotypes. Due to some internal staffing shortages and turnover of personnel, the completion of the validation has been delayed but is expected to be completed by 12/31/2011.

Massachusetts is well situated to participate in programmatic and outbreak response activities that span several agencies. The Massachusetts Bureau of Laboratory Science (BLS) is co-located with the Bureau of Infectious Disease (BID) and the Food Protection Program (FPP) at the HSLI. Together these three components of MDPH form the Working Group on Foodborne Illness Control (WGFIC). The group meets twice monthly to discuss active investigations of outbreaks of foodborne illness, and clusters of illness related by matching PFGE patterns. Shared network databases allow information to be transferred and shared among all members of WGFIC. The BLS infrastructure enables our internal LIMS system to communicate directly with the epidemiologist's data management system (MAVEN), and with local hospital laboratories electronically. This allows critical information such as test results and reports to be transferred in near-real time, every 30 minutes, from the local laboratories to BLS and MAVEN.

Our expertise resulted in Massachusetts being one of the first states to confirm an infection with *E. coli* O104:H4 in a patient who had travelled to Germany. A stool specimen, GN broth and several isolated colonies were submitted to HSLI from a local clinical laboratory. Using our current protocols we were able to identify the organism as being Shiga toxin positive and also belonging to O104:H4. The isolate was sent to the PFGE laboratory for comparison to the outbreak strain from Germany and was found to be indistinguishable. The isolate was then sent to CDC for PCR and other additional tests. It has since been mentioned in numerous publications about the German outbreak. While this is a success story, it would have been even more so if Massachusetts had been routinely running PCR for STEC. It would have given Massachusetts and the CDC more timely information on specifics of the toxin profile. Implementing a PCR assay in Massachusetts can greatly enhance our testing capacity and allow us to provide better information faster.

Massachusetts requests funding for 0.5 FTE for molecular test development of PCR for Shiga toxin-producing organisms, as well as start-up costs for test development including primers, probes, enzymes and other associated reagents. We are requesting funding for shipping costs associated with the increased cost of shipping Shiga toxin positive isolates and broths as category A infectious substances. This funding will be used to offset costs for local laboratories to send

isolates and broths to the HSLI as well as BLS to send isolates to CDC for confirmation. Massachusetts requests funding for beads and other associated reagents for IMS processing of samples.

b) Operational Plan

Activity 1: Increase the number of STEC isolates, stools, or broths submitted for testing and decrease the travel time from collection or isolation to receipt at HSLI.

Year 1 (1/1/12-12/31/12) staff will:

- Distribute a clinical advisory requesting all clinical laboratories in the state perform a test for detection of Shiga toxin in all stool specimens in children under the age of five, or send those stool specimens to HSLI for Shiga toxin detection.
- Request stool specimens on all HUS patients where no causative agent has been identified.
- Determine the baseline time in number of days for an isolate, broth, or stool to be received at HSLI following collection or isolation.

Years 2-5 (1/1/13-12/31/16):

Further activities will be planned for subsequent years if the desired result is not achieved after instituting the abovementioned actions.

Activity 2: Enhance testing capability by implementing a PCR-based testing platform for STEC.

Year 1 (1/1/12-12/31/12) staff will:

- Implement a PCR based test for STEC genes (i.e. *stx*₁, *stx*₂, *eae*, *ehxA*)
- Validate the method in accordance with APHL guidance for validating a non-FDA approved test.

Years 2-5 (1/1/13-12/31/16):

The validated method will be put into routine use for all stool specimens, broths, and isolates received from the local labs, suspected of containing an STEC

Activity 3: Routinely implement IMS technology to enhance likelihood of detection of STEC

Year 1 (1/1/12-12/31/12) staff will:

- Routinely use already validated O157 non-O157 bead sets in the top six serotypes to enhance the recovery of STEC from clinical stool specimens.

Years 2-5 (1/1/13-12/31/16):

These methods will continue in general use until other methods are developed and suggested as a replacement for current methods with the advice of our federal partners. Additional projects and validations with CDC will continue to occur as identified.

c) Measures of Effectiveness/Measureable Goals

Measures of Effectiveness

Activities 1-3:

- As a result of the distributed clinical advisory, an increase in clinical laboratories testing occurs for detection of Shiga toxin in all stool specimens in children under the age of five.
- The baseline time in number of days is determined for an isolate, broth, or stool to be received at HSLI following collection or isolation.
- A PCR-based detection method is researched, validated and implemented.
- IMS technology continues to be used routinely for stool specimens, broths, and mixed cultures.
- New bead sets are validated as new serotypes are identified and bead sets become available.

Measurable Goals

The following table illustrates the burden of illness in Massachusetts for the time period 7/1/10 to 6/30/11.

	Numbers received in the public health laboratory	Numbers sent to CDC for Isolation and/or Serotyping		STECs Identified	Person Hours* (estimating 3 total hours per specimen)
			O157	62 (including positive repeats)	186
Cultures/ Isolates	67	46	Non-O157	116 (including positive repeats) (Plus 17 shiga toxin positive, no organism isolated)	348
Specimens/Broths	258	0	Negative/ Repeat Tests	147	441
Total	325	46	Total	325	975

ATTACHMENT 2

FOODBORNE DISEASES

F. CaliciNet – Capacity for molecular identification of human caliciviruses

a) Background, Need and Understanding

Massachusetts is a small but densely populated state with 6.5 million residents. The greater Boston Area is ranked the 10th largest metropolitan area in the U.S. with ~4.5 million residents. Its largest city, Boston, is a port that is home to four major cruise ship lines sailing to Canada, multiple New England ports, Europe, Bermuda and the Caribbean. Within the city of Boston, the historic Faneuil Hall alone receives 20 million tourists each year. Massachusetts has more than 520 registered nursing and rest homes. Finally, according to the National Restaurant Association and U.S. Census Bureau data from 2009, there were 14,274 restaurants across the state. Based on prior national outbreak surveillance data collected by CDC, Massachusetts provides numerous settings that would benefit from enhanced surveillance of viral gastroenteritis and this information would in turn assist with determining the burden and trends of epidemic norovirus and its attribution to settings, transmission routes, and food vehicles.

With an estimated 5.5 million cases annually in the US, norovirus is recognized as one of the most common pathogens causing foodborne illness. In 2007, the city of Boston alone documented 3,700 emergency room visits for a gastrointestinal illness within a six-week period. Historically, approximately 100 samples per year have been submitted to the Hinton State Laboratory Institute (HSLI) from outbreak investigations. Currently, the Massachusetts Department of Public Health (MDPH) submits representative specimens from suspected norovirus outbreaks to the New York State Department of Health Wadsworth Center for sequencing and submission to the CaliciNet national database. Between 7/1/10 and 6/30/11, MDPH submitted 15 specimens from four outbreaks for testing. Of these, 33% were positive and had sequences submitted to CaliciNet. The Massachusetts Bureau of Laboratory Science (BLS) has the both the expertise and the capacity to perform the assay at the HSLI. The BLS was recently funded for a multi-disease purpose laboratory (MPL) staff position via the ACA ELC grant to perform real-time detection PCR for noroviruses. This staff position will also be responsible for implementing sequencing of norovirus samples followed by training surge molecular staff on both of these assays. Surge molecular staff are funded by both influenza base ELC and PHEP grants. Equipment (both PCR platforms and Beckman Coulter sequencing platforms) are maintained by service contracts funded by the PHEP cooperative agreement.

To improve on Massachusetts' ability to identify and characterize unlinked viral gastroenteritis outbreaks or those linked to foodborne transmission, the BLS will add laboratory testing capacity to identify and strain-type noroviruses to strengthen the outbreak investigation capability of the Bureau of Infectious Disease (BID) epidemiologists and the Bureau of Environmental Health's (BEH) Food Protection Program (FPP). As part of this effort, norovirus laboratory staff will join the Working Group on Foodborne Illness Control (WGFIC) to assist with control efforts by providing rapid laboratory results to help manage and control both food safety and food security

incidents. The WGFIC is a collaboration among laboratorians, epidemiologists, and food protection officials. The group meets a minimum of twice each month to discuss all clusters and outbreaks of foodborne illness in the state. In addition to in-person discussions of all active investigations, the group has access to databases that allow results to be shared in real time. Once CaliciNet certified, BSL is uniquely positioned to cross-train additional testing staff to perform all molecular testing assays for foodborne viruses (e.g., human caliciviruses such as noro- and sapoviruses) following the initial implementation of real-time detection PCR for detection and gene sequencing for genetic characterization. Finally, BSL will upload all human calicivirus data in real time to CaliciNet to enhance the ability of Massachusetts to participate in tracking multi-state and international outbreaks.

b) Operational Plan

Activity 1: Develop laboratory capacity to allow for participation in CaliciNet (National Norovirus Outbreak Surveillance Network) which uses nucleotide sequence analysis for genotyping of norovirus and sapovirus strains.

Massachusetts was recently funded for a multi-disease purpose laboratory (MPL) staff position via the ACA ELC grant. This position will be the primary point of contact for norovirus laboratory testing. Although a representative from MDPH attended the May 2011 CaliciNet training and was in the process of becoming certified, the position has since been vacated. It is expected that Massachusetts will be able to attend the next APHL/CDC CaliciNet training in June 2012. The new person will be responsible for ensuring that the HSLI becomes a certified CaliciNet site and for training additional surge testing staff. Funding on the ACA ELC grant was received to perform detection of noroviruses via real-time detection PCR. ACA ELC funding was also received to add the new norovirus diagnostic PCR test to the existing LIMS (IML and BtB) for the two different laboratories responsible for processing and testing of stool specimens and food isolates for noroviruses.

Year 1(1/1/12-12/31/12):

- Prior to 6/1/12, staff will complete validation of the norovirus real-time detection PCR assay on the ABI 7500 Fast Dx platform.
- By 12/31/12, staff will have fully implemented norovirus conventional PCR and sequencing of all norovirus positive specimens followed by real time uploading of the sequencing data into CaliciNet.
- Beginning 1/1/12, norovirus staff will join the WGFIC meetings.
- Yearly, one staff laboratorian will attend the annual CaliciNet Users Group meeting (TBD)
- By 12/31/2012, norovirus testing staff will identify and participate twice yearly in proficiency testing program for PCR detection of noroviruses and maintain an 80% or above testing score.

Years 2-5 (1/1/13-12/31/16):

In real-time, staff will collaborate with epidemiologists to receive and test by norovirus real time detection PCR at least 5-6 specimens per each outbreak. In real-time, staff will perform sequencing on positive specimens and upload at least two sequences per each outbreak to

CaliciNet. Staff will collaborate with CDC lab staff on testing and implementing new protocols for CaliciNet. Twice yearly, norovirus testing staff will participate in proficiency testing program for PCR detection of noroviruses.

c) Measures of Effectiveness/Measurable Goals:

- 100% of the ELC funds for this activity is used to implement laboratory techniques to support CaliciNet.
- In real-time, the number of outbreaks (≥ 1 specimens) tested for norovirus (percentage with likely foodborne transmission) along with the total number of norovirus negative outbreaks are monitored and reported to NORS, the national outbreak response system.
- Twice yearly, norovirus testing staff identify and participate in proficiency testing program for PCR detection of noroviruses and achieve a 80% or better score for CLIA certification.
- All clusters of foodborne illness suspected of being caused by norovirus (100%) are discussed and investigated by the WGFIC.
- At least two sequences per each outbreak are uploaded in real-time to CaliciNet.
- One laboratorian attends the annual CaliciNet Users Group meeting.

ATTACHMENT 2

FOODBORNE DISEASES

G. NARMS – Surveillance Activities – reporting of foodborne events to CDC

a) Background, Need and Understanding

Massachusetts is the fourteenth most populous state in the nation, with over six million people distributed over 351 cities/towns. Only five of these cities/towns have populations greater than 100,000, while approximately 270 have populations less than 20,000 (US Census). Data for Massachusetts show that the five most populous cities or towns are Boston, 617,594; Worcester, 181,045; Springfield, 153,060; Lowell, 106,519; and Cambridge, 105,162.

The largest county is Middlesex, with a population of 1,503,085. The other counties in the top five include Worcester (798,552), Essex (743,159), Suffolk (722,023), and Norfolk (670,850).

Please see below table for a subset of notifiable, communicable diseases for 2010

Selected Notifiable	# Confirmed	# of Probable	# of Suspect Cases
Salmonellosis	1263	0	1
Shiga toxin-producing organism	62	16	15
Shigellosis	213	0	2
Listeriosis	27	0	2
Vibrio species	53	0	3

Human illness surveillance

Massachusetts has participated in the National Antimicrobial Resistance Monitoring System (NARMS) program since 1996. Since then, the Bureau of Laboratory Science (BLS) at the Hinton State Laboratory Institute (HSLI) has routinely provided quarterly shipments of 5% (every 20th isolate identified) of *Salmonella* species (non-Typhi), *Shigella*, and *E. coli* O157. We also send each isolate of *Vibrio* non-cholera, and *Salmonella* Typhi. In addition, each isolate of *Listeria monocytogenes* and *Vibrio cholera* is submitted to the CDC as they are identified. HSLI sends outbreak isolates identified as part of multi-state outbreaks as requested by CDC. Massachusetts recognizes the public health significance in tracking antimicrobial resistance trends in enteric pathogens and is committed to continuing to participate as we have in the past.

The BLS also proposes to test non-O157 STEC organisms in conjunction with local or multi-state outbreaks. We recognize the importance of non-O157 STEC, and that as infections by these organisms are increasing, the trends in resistance profiles are of equal value to public health. Massachusetts will send a subset of all non O157 STEC isolated from outbreaks to the CDC NARMS program for testing.

In addition to our past submissions of quarterly samples and outbreak isolates from multi-state outbreaks as requested by CDC, Massachusetts will propose to send representative isolates from clusters and outbreaks that are local to Massachusetts. Valuable information can be learned from studying trends in resistance profiles seen locally, and also comparing them nationally.

Massachusetts requests funds for the cost of media to support the growth of these organisms in the lab and while they are in transit to CDC. We also request funds to support packaging supplies, and costs associated with shipping the isolates. This will include the extra costs in material and paperwork and mechanism of shipping for category A organisms.

Retail meat surveillance

Foodborne illness is a national problem. According to CDC, in 2011 nearly one in every six Americans is sickened annually from foodborne pathogens. The US has a very strong system to track the DNA fingerprint patterns as a part of PulseNet. PulseNet has proven invaluable in identifying clusters of illness, and linking implicated food products to infected cases resulting in recalls and Massachusetts has been a key player in the PulseNet program since it began in 1996. What is needed is a more robust system to identify contaminated food PRIOR to it causing illness. Good data is hard to find regarding the contamination levels of raw meat products sold at retail, especially for salmonella and campylobacter in poultry products. While obtaining isolates from raw poultry products may not lead to recalls until there is a zero tolerance policy for salmonella and campylobacter, it will create a known library of PFGE patterns that can then be used during outbreak investigations. By increasing the product commodities and sample sizes that are currently tested as a part of the retail meat surveillance program, we will have a better overall indication of the true burden of pathogens in these commodities across the nation.

Massachusetts proposes to participate in the Retail Food Surveillance Project in 2012. Massachusetts has not participated in this project in the past, but we are now well positioned to do so. In 2010-2011, an EID fellow, stationed at the HSLI, undertook a pilot retail meat surveillance project. This project involved purchasing raw whole broiler chickens from local markets and testing them for *Salmonella* (following BAM protocols) and *Campylobacter* (using a protocol derived from a CDC communication). The goal of the project was to compare the overall bacterial load of chickens from large chain retail markets, fresh kill bird markets, and organic high end retail markets. A second goal was to expand our library of PFGE patterns of isolates from raw chickens. All unique isolates were tested by PFGE and uploaded to the PulseNet National Database. They were compared locally and nationally against all human isolates. The project resulted in 18 different unique *Salmonella* PFGE patterns (of seven different serotypes) and 29 different unique *Campylobacter* PFGE patterns being added to our local database. It also resulted in one local market being investigated by the Food Protection Program (FPP). The overall findings were presented in a poster at the IAFP conference in July of 2011, and a manuscript is currently being prepared for publication.

Massachusetts requests funding to continue the pilot project as part of the retail meat surveillance project. We will seek 0.5 FTE to complete the work, as well as costs associated with food sampling and collection, rapid screening methods (e.g. BAX and Vidas kits), routine bacteriological culture reagents and supplies, and PFGE reagents. All identified isolates will be sent to the FDA's Center for Veterinary Medicine (CVM) Office of Research for species and serotype confirmation, antimicrobial susceptibility testing, and genetic analysis as described in the announcement.

b) Operational Plan

Activity 1: Human illness surveillance

Year 1 (1/1/12-12/31/12):

- All isolates that meet the specified criteria will be correctly identified and submitted.
- All calls will be attended by appropriate laboratory and epidemiology staff.
- All additional isolates requested by NARMS will be submitted to NARMS.
- The lab will participate in the CDC *Salmonella* QA/QC Program; discrepant results will be investigated and corrective actions will be documented.

Years 2-5 (1/1/13-12/31/16)

Massachusetts will continue to participate in all NARMS related activities as required by the program

Activity 2: Retail meat surveillance

The following plan should be considered a draft and subject to change as guidelines are provided from federal partners.

Year 1 (1/1/12-12/31/12):

- Two whole chickens (or equivalent meat product) will be collected every other week during the grant period. Products will be purchased on Mondays by staff at HSLI and brought directly to HSLI. Appropriate chain of custody will be adhered to. Locations for collections will be determined prior to the start of the project with input from federal partners.
- Collected chicken or alternate meat product will be processed into up to 10 sub-samples, each enriched in accordance with FDA BAM protocols for *Salmonella* (pathogen of interest may be modified by CDC or FDA partners).
- After 24 hours incubation, each subsample will be screened by both BAX and Vidas, while the culture is continued following appropriate protocols.
- Any positive isolates will be serotyped or speciated, and tested by PFGE in the Massachusetts PFGE lab. PFGE fingerprints will be maintained in the local Massachusetts database and uploaded to the national PulseNet database if indicated by federal partners.
- Each representative isolate will also be sent to CVM's Office of Research for species and serotype confirmation, antimicrobial susceptibility testing, and genetic analysis.

Years 2-5 (1/1/13-12/31/16):

The purchasing timeline will be adjusted based on feedback from federal partners and the results of the project from Year 1. All products obtained will continue to be tested in accordance with established protocols for organisms selected for study. This most likely will continue to be FDA BAM protocols for *Salmonella*. Isolates will continue to be tested by PFGE and added to the local database. Representative isolates will continue to be submitted to CVM's Office of Research.

c) Measures of Effectiveness/Measurable Goals:

Measures of Effectiveness

Activity 1:

- All 2012 isolates that meet the specified criteria are correctly identified and submitted.
- All 2012 calls are attended by appropriate laboratory and epidemiology staff.
- All additional isolates requested by NARMS are submitted to NARMS.

Activity 2:

- Products are purchased every other week and submitted to the lab on Mondays.
- Products are tested in accordance with FDA BAM protocols for *Salmonella*, (or other pathogens if indicated by federal partners).
- Isolates are tested by PFGE and added to the local database.
- Representative isolates are submitted to CVM's Office of Research.

Measurable Goals

The following table outlines the number of isolates received from 7/1/10 to 6/30/11, and the numbers submitted to CDC as part of the NARMS program. Please note, Massachusetts underwent significant staffing changes and shortages in 2010-early 2011. We missed a shipment of isolates that should have been included in the quarter three submission. Because of these staffing changes, we also did not send our routine paratyphi A isolates (we did not have any paratyphi C). As of April 2011 staffing issues have been rectified and are committed to continuing to participate in the program by submitting the appropriate numbers of isolates.

Pathogen	Total # of routine human isolates submitted to NARMS	Total # of routine human isolates received by site laboratory	Percentage of isolates shipped to NARMS	Isolate submission frequency	Number of conference calls attended
Non-typhoidal <i>Salmonella</i> example	34*	1264	2.6% (**4.1%)	quarterly	4
<i>Salmonella</i> Paratyphi A and C	4*	16	25%(*100%)	quarterly	4
<i>Salmonella</i> Typhi	17	31	54%	quarterly	4
<i>Shigella</i>	4*	176	2.2% (**4.5%)	quarterly	4
<i>E. coli</i> O157	1*	56	1.7% (**5.3%)	quarterly	4
Non-toxigenic <i>Vibrio</i>	11	36	30%	quarterly	4

* due to staffing shortages and turnover in the lab, our 3rd quarter 2010 isolates and all paratyphi A isolates did NOT get submitted.

(**percentage if all of the appropriate isolates had been submitted)

ATTACHMENT 4

HEALTHCARE ASSOCIATED INFECTIONS

A. Reporting and Ensuring the Quality of Healthcare-Associated Infection Data

a) Background, Need and Understanding

Hospital associated infections (HAIs) are estimated to affect 1.7 million Americans and cause 99,000 deaths annually in US hospitals. Through a systematic and comprehensive approach, Massachusetts has achieved better or equal rates of HAIs compared to other states. However, since infections are preventable and addressing this winnable battle leads to better health outcomes, and lower health care costs, Massachusetts strives to further reduce HAI rates.

Massachusetts has utilized NHSN for tracking central line associated blood stream infections, and surgical site infections following knee replacement, hip replacement, hysterectomy and CABG surgeries in acute care hospitals since 2008. In 2010, ambulatory surgical centers (ASC) began reporting on herniorrhaphy procedures through NHSN. ELC, ARRA and ACA funding has expanded epidemiology capacity in the area of HAI. Currently, the epidemiology team consists of a senior epidemiologist responsible for HAI surveillance and enhanced hepatitis surveillance, and two general epidemiologists who are responsible for HAI activities in addition to core epidemiology responsibilities. The HAI team analyzes NHSN data, follows up on healthcare associated outbreaks, understands epidemiology of multidrug resistant organisms, assists in analysis of data collected through collaboratives and completes other appropriate epidemiologic activities as outlined in the Massachusetts five year plan.

American Recovery and Reinvestment Act (ARRA) funding allowed Massachusetts to put more focus on the quality of data entered into NHSN. A data manager funded through ARRA was hired at the end of 2009. Massachusetts can now provide hospitals with a single point of contact for questions specific to Massachusetts NHSN data. Massachusetts provided regular, clear communications to the acute care hospitals around data quality with the creation of bimonthly hospital-specific reports that review internal quality issues such as missing denominator data or potential data entry errors. As a result of this ongoing work, Massachusetts very quickly applied new analysis methods made available by CDC with limited excluded data due to missing or inappropriate values. Other staff members have been able to focus on creating reports for community partners. ARRA funding supported a Massachusetts contract with the John Snow Institute (JSI) to evaluate the completeness, consistency and accuracy of mandatory reporting to NHSN. JSI staff will have visited each acute care hospital to review laboratory information and perform chart reviews by the end of this calendar year. Through these visits, systematic errors in the application of NHSN case definitions have been identified in various locations. The team has provided clarification of state reporting requirements and NHSN user requirements. These validation visits insure that acute care hospitals are equally and accurately reporting events to the system. Funding for validation activities and the data manager ends in 2011. Through the funding period, processes for data cleaning and validation have been tested and improved. Programs have been written to create automated data cleaning reports, and communications and data quality processes have been streamlined. However, data quality can always be improved.

Timely reporting is a newly identified issue. Hospitals are provided with a 60 day window in which to report data. Monthly reports created for community partners show that for data run in September, only 57% of the acute care hospitals had entered data for July and 88% had entered data for June. Particularly for our prevention collaborative partners, this limits their ability to evaluate the effectiveness of the work they are doing. Massachusetts proposes the creation of a contract epidemiologist position to continue and expand data quality initiatives. This position will continue the described activities of the data manager, as well as the validation activities currently in application through the Massachusetts contract with JSI. In year one, the contractor will provide increased focus on timeliness of reporting and determine the best method to continue validation activities. In years two through five, validation activities will be expanded to ASC sites and potential data issues related to expanded reporting through NHSN, such as immunization of healthcare worker data, will be explored.

In December 2010, MDPH staff conducted an electronic survey with current NHSN users at acute care hospitals regarding the time burden of data entry in NHSN, available staff resources, and utilization of NHSN's current electronic upload capabilities. Responses were received from staff of 65 of 73 acute care hospitals. On average, facilities had 1.49 full-time infection preventionists (IPs, range: 0-5) who dedicated an average of 7.49 hours per week (range: 0-40) collecting and entering data into NHSN. The amount of time spent by each facility on NHSN activities varied by facility bed size as anticipated: larger facilities spent more time on NHSN activities than did smaller ones. Of the 65 facilities that responded to the survey, 45% of them (n=29) reported uploading at least SSI denominator data. At that time, all reported uploading through files such as CSV or TXT files. No hospitals used the available Clinical Document Architecture (CDA). Although CSV or TXT uploads appeared to save some time for most hospitals, creating these files still involved a large time commitment on the part of the infection prevention or support staff. Of the 36 facilities that did not use electronic upload, 11 reported that they were small hospitals and/or had little data to enter, seven facilities identified lack of IT support as a problem, and five acknowledged a lack of funding as a barrier.

This survey illustrated the burden of data entry on hospital staff to enter required data into NHSN. Forthcoming CMS regulations with more requirements will further increase the burden upon hospitals for data entry. The survey also showed a willingness by the hospitals to use electronic systems to alleviate some of this burden; even a simplistic electronic upload, the time for data entry for most hospitals was reduced compared to hospitals of similar sizes.

Laboratory information is already being transmitted electronically to MDPH by the majority of the 73 hospital laboratories in the state. In 7/2008, MDPH passed regulations mandating the use of its electronic laboratory reporting (ELR) infrastructure for reporting notifiable conditions. As of 11/2011, 61 of 73 hospital laboratories and two commercial laboratories are fully certified to transmit results using ELR. MDPH's PHIN-compliant ELR infrastructure establishes secure, electronic messaging between clinical laboratory applications with MAVEN. Participants utilize a web based user interface to create a mapping between MDPH selected LOINC and SNOMED codes and their local equivalents. These mappings are used to translate native codes into their LOINC and SNOMED equivalents before data are transmitted into the MDPH data store.

Institutions may transmit messages using the HL7 2.3.1 ORU RO1 or a MDPH developed message format that is transformed into HL7 2.5.1. This same infrastructure supports the transmission of hospital ED data for emergency preparedness efforts.

Most of the data required by NHSN are not available within a hospital laboratory data system. Examples include NHSN procedure types, procedure codes, operative time, wound class, emergency versus scheduled status, and use of anesthesia. NHSN reporting requires collating data from multiple sources including laboratory data, operating room data, ICD-9 codes, and other hospital databases. A system is needed to collate data from the various locations and siphon them to NHSN. A possible solution exists in the Electronic Support for Public Health (ESP) initiative. As a partner in one of the CDC-awarded Centers for Excellence in Informatics, MDPH is actively engaged in leveraging existing technical solutions, principally MDPH's ELR infrastructure, to electronically receive pertinent health information to support case investigations. As described in MMWR (MMWR: 2008;57:373-6) and JAMIA (2009;16:18 – 24), this ESP initiative has successfully developed algorithms to automatically send case reports via MDPH's ELR interface. These reports add substantial clinical detail over and above conventional electronic laboratory reports. They use the richness of the data captured by electronic medical record systems to be able to distinguish acute from chronic cases (e.g. acute hepatitis C), to report on purely clinical diagnoses (e.g. culture-negative tuberculosis), and to provide important corollary information such as patient and clinician contact details, pregnancy status, symptoms, and prescribed treatment.. ESP currently has algorithms for the following notifiable diseases: syphilis, gonorrhea, Chlamydia, pelvic inflammatory disease, tuberculosis, hepatitis A, acute hepatitis B, acute hepatitis C, Lyme disease, and pertussis. Data are sent to MAVEN utilizing HL7 and PHIN-MS via the ELR infrastructure. ESP sits on top of a hospital's electronic medical record and gathers information from all hospital systems. This same technology may be of use in gathering NHSN data. The Cambridge Health Alliance (CHA), an acute care network with three hospital locations reporting to NHSN, currently has ESP in place. CHA has been sending HL7 messages to MDPH through our ELR system since November of 2006, and was the first hospital system fully reporting through ELR. MDPH proposes collaboration with CHA to explore the possibility of using ESP to collect and submit NHSN data, beginning with surgical site infection data. In 2010, CHA submitted data to NHSN on 204 knee replacement, hip replacement, and hysterectomy procedures. Hospital IPs report spending roughly 10 hours a month manually collecting required data elements for this reporting, not including data entry time. As more reporting elements are required from CMS, automation is essential for surveillance and sustainability. cursory investigation shows that most data elements are available through CHA electronic systems. Year one would focus on identifying where key data resides at CHA, linking those data with ESP. Years two and three would be used to create systems to organize and interpret the data and create and validate SSI denominator reports. Finally, in years four and five, the HL7 2.5.1 ELR message and HL7 CDA documents would be created and validated, both by MDPH and through the CDA validator. While applying this system to the SSI data, the feasibility of using the system for other reporting elements outside of the current state mandate, such as LabID events reporting, will be explored.

b) Operational Plan

Activity 1: Conduct Activities to Ensure the Quality of Data Reported to NHSN.

Through a contract epidemiologist, Massachusetts will be able to continue and expand existing data quality efforts. These efforts include continued regular communication with hospitals regarding data completeness and quality and continued evaluation to assess proper application of NHSN surveillance definitions. New initiatives in year one will include evaluation of reporting timeliness and methods by which facilities can improve their own data quality. In years 2-5, new data measures, such as influenza immunization of healthcare worker data, required by both Massachusetts and CMS, will be evaluated to determine potential data quality issues.

Program staff will:

- Continue to provide acute care hospitals with bimonthly reports on data completeness and quality and provide feedback on how corrections can be made.
- Create a quarterly report on timeliness of reporting to be sent to acute care hospitals.
- Create a document for self-guided data quality checks to be used by participating facilities and distribute via the website.
- Resume creation of quarterly newsletters for acute care hospitals which include updates on potential data quality questions and problems.
- Determine the quality and completeness of data submitted to NHSN, assess the consistency and accuracy of case finding and the application of NHSN surveillance definitions for acute care hospital data, and begin implementing the data validation protocol in acute care hospitals independently.
- Analyze data submitted on pathogens associated with reported HAI events to check for proper classification of events and to examine antimicrobial resistance trends.
- Continue to contact ambulatory care centers biannually regarding data completeness and quality.

Year 1 (1/1/12 –12/31/12):

- By 2/1/12, existing team will create a plan for continued data validation in acute care hospitals and extended data validation for additional sites reporting through NHSN.
- By 2/1/12, contract position will be created and posted.
- By 3/1/12, contractor will be hired.
- By 6/1/12, self guided data check document will be created.
- By 6/1/12, a report on data timeliness will be created and information communicated to facilities.
- By 12/31/12, pathogen data will be analyzed and presented to the leadership group.

Years 2-5(1/1/13-12/31/16):

Throughout years 2-5 all activities above will continue. By 2/1/13 validation of ASCs will be initiated. By 1/1/14 data entered for healthcare worker safety module will be evaluated for potential data quality issues and an appropriate method for addressing those issues will be determined.

Activity 2: Development of Integrated Solutions for Electronic Laboratory Reporting of Reportable Communicable Diseases and HAI Events

Massachusetts proposes collaborating with CHA and ESP to determine feasibility of utilizing ESP for electronic reporting of NHSN SSI data. Use of ESP for reporting elements outside of the current state mandate, such as LabID events reporting, will also be explored.

Program staff will:

- Convene a working group to explore the advantages and issues with using ESP to extract, collate, and transmit data from CHA to NHSN.
- Act as a liaison between NHSN, MDPH, ESP and CHA to identify data elements and potential data quality issues for mapping.
- Collaborate in the development of a specification for SSI denominator reports.
- Act as a liaison to NHSN to identify a CDA format, HL7 specification, and receiving portal for SSI case reports and / or denominator reports. Collaborate with NHSN, CHA, and ESP on electronically validating report format, messaging protocol, and contents.
- Act as program expert to answer any question related to NHSN use and current utilization by MDPH.
- Communicate with CDC regarding process to identify any issues or potential strengths.

Year 1 (1/1/12 –12/31/12):

- By 6/1/12 all SSI data elements are identified in CHA electronic systems.
- By 12/31/12 all identified data elements are mapped to ESP system.
- By 12/31/12 feasibility of data collection for LabID event reporting is explored.

Years 2-5 (1/1/13-12/31/16):

By the end of the five year grant period, HL7 message will be created and validated to transfer SSI data from CHA system to NHSN. Sharable artifacts will be created that may be used in replicating this effort in other locations with differing infrastructure and products

c) Measures of Effectiveness/Measurable Goals

- Six sets of data cleaning reports are distributed to hospitals.
- Two data quality checks are completed with ASCs. Validation activities are completed with a minimum of 12 hospitals.
- Availability of data improves from 88% to 98% for data 90 days past event/procedure date.
- Availability of data improves from 57% to 75% for data 60 days past event/procedure date.
- Remaining 13 of 74 hospital laboratories are reporting communicable disease data via HL7 2.3.1 ELR message to Massachusetts MAVEN system.
- SSI data elements in CHA system are identified and mapped to ESP.HL7
- CDA document is created for reporting SSI denominator data to NHSN.

B. Improving Antimicrobial Use to Decrease Antimicrobial Resistant HAIs and Clostridium difficile infections

a) Background, Need and Understanding

The role of the Massachusetts Department of Public Health (MDPH) is essential in accelerating progress towards the elimination of healthcare associated infection (HAI). MDPH is uniquely positioned to monitor HAI trends, identify and investigate outbreaks, recognize emerging pathogens and unsafe medical practices, ensure the implementation of known prevention strategies and assist in the identification of prevention needs. The Massachusetts HAI Prevention and Control Program is a collaborative of major components of the MDPH, including the Bureau of Healthcare Safety and Quality (the state regulatory and survey agent), the Betsy Lehman Center for Patient Safety and Medical Error Reduction and the Bureau of Infectious Disease (BID). Strategic planning, development, program advancement and the ongoing coordination of cross bureau activities are directed by a Leadership Group that includes senior bureau staff. The activities described in this proposal have been developed in consultation with the independent multidisciplinary HAI Technical Advisory Group and key external partners including the Massachusetts Coalition for the Prevention of Medical Errors, Massachusetts Senior Care Association, and MassPRO (the state quality improvement organization). The activities are consistent with the goals and metrics identified in the Massachusetts five year plan for surveillance, prevention and elimination of HAI in Massachusetts.

http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/hai_plan_implementation.pdf

THE CASE FOR ANTIBIOTIC STEWARDSHIP IN LONG TERM CARE FACILITIES

Clostridium difficile accounts for 15-25% of all episodes of antibiotic-associated diarrhea (AAD). Reported rates for *C. difficile* infection (CDI) range from 1 to 10 per 1,000 discharges and 17-60 cases per 100,000 patient days. *C. difficile* is responsible for a spectrum of infections including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon which can, in some instances, lead to sepsis and even death. Increasing age has been identified as a risk factor for *C. difficile* infection; most individuals with symptoms of *C. difficile* are older than 60 years of age. It is, therefore, not surprising that this infection also commonly occurs in long term care facilities (LTCFs). One study revealed a prevalence of nursing home-onset CDI of 263,000 cases, resulting in approximately \$2.2 billion in excess costs, and 16,500 deaths annually.

Several risk factors for acquiring *C. difficile* in LTCFs have been identified, including the use of antimicrobials. Antimicrobial use, especially the use of cephalosporins and fluoroquinolones has been associated with *C. difficile* acquisition. Antimicrobial agents are among the most frequently used drugs in LTCFs, accounting for up to 40% of all systemic drugs prescribed. Surveys of LTCF residents found an antibiotic usage point prevalence of approximately 7%-10%, with antibiotics frequently given for extended periods of time. A substantial portion of the antimicrobial use in LTCFs is considered inappropriate, with recent reports indicating that 25% to 75% of systemic antimicrobials are prescribed inappropriately. LTCF residents are more susceptible to antibiotic resistance. Smith, et al. note that the frequent use of antibiotics in long term care settings has led to the selection of a resistant flora, and the proximity of residents and contact between residents and healthcare workers facilitates the spread of these organisms.

Urinary tract infection (UTI) is the most common infection in residents of LTCFs. Current consensus guidelines from organizations suggest that asymptomatic UTIs should not be treated, taking into account the high percentage of re-colonization after treatment, the potential

complications of therapy, including increased incidence of *C. difficile*, and the risks of selecting for antibiotic resistance. Prospective, randomized comparative trials of antimicrobial therapy or no therapy, in which elderly nursing home residents with asymptomatic bacteriuria were enrolled, consistently document no benefits of antimicrobial therapy. Experts have voiced the need for increased education for providers who care for patients in LTCFs about the high frequency and appropriate management of asymptomatic bacteriuria, the diagnostic uncertainty in identifying symptomatic infection and appropriate treatment of symptomatic infection.

There have been increasing calls by the infectious disease (ID) and pharmacy communities for the development of programs that encourage the proper use of antibiotics, particularly in LTCFs. Comprehensive antibiotic stewardship programs (ASPs) have consistently demonstrated a decrease in antimicrobial use (22%–36%), with annual savings of \$200,000–\$900,000 in both larger academic hospitals and smaller community hospitals. ASPs are relatively new in LTCFs, but are important to control antibiotic overuse and antibiotic resistance. Smith, et al. propose that the implementation of ASPs, which promote the appropriate use of antimicrobials, has the potential to limit antimicrobial resistance in long term care settings, while improving treatment efficacy, minimizing drug-related adverse events and reducing treatment-related costs. **Error! Bookmark not defined.**

Addressing issues of optimal antibiotic use should be of great concern to LTCFs. CMS guidance for state LCTF surveyors specifically cite drug utilization review.

Urinary tract infection is also a Nursing Home Quality Measure that CMS tracks and nursing homes must report on and respond to during their annual survey. Hospitals will benefit from improving antibiotic use in LTCFs, where they frequently transfer patients. Transfers to hospital account for 25% to 50% of nursing home discharges. Studies have found that 26%–38% of such transfers have infection as a primary diagnosis. We would thus anticipate that ASPs in LTCFs would decrease hospitalizations due to both *C. difficile* and antimicrobial resistant infections. Furthermore, improved antibiotic use would result in fewer residents with colonization of *C. difficile* and other antibiotic-resistant bacteria, reducing the likelihood of spread of such organisms within the infection following admission to an acute care facility.

AN OPPORTUNITY TO ADDRESS THE NEED

Massachusetts is in a unique position to demonstrate the impact of a learning collaborative addressing ASPs in LTCFs, and in the transfer of patients between hospitals and LTCFs.

Ongoing collaborative relationships

The proposed work plan will benefit from a long history of collaboration among key healthcare quality stakeholders in Massachusetts. The Massachusetts Coalition for the Prevention of Medical Errors (the Coalition) will be charged by MDPH with leading the work of the proposed Collaborative. The Coalition is a multi-stakeholder membership organization whose mission is to improve patient safety and eliminate medical errors. The Coalition's Executive Director served on the MDPH Infection Prevention Expert Panel, sits on the HAI Technical Advisory

Group (TAG) and is a member of their Infection Prevention Leadership Group. The Coalition has worked under contract to the Massachusetts MDPH on infection prevention initiatives:

- Targeting practice improvement and the elimination of HAIs with funding from MDPH with state funding (2007-2009);
- Reducing *C. difficile* infection hospital-wide and central-line associated blood stream infections in ICUs, through a CDC grant with ARRA funding(2009-2011)
- Developing partnerships between hospitals and LTCFs to reduce *C. difficile* infections, with the MA Senior Care Association and MDPH with CDC funding (2011-2012)

The Coalition also works collaboratively on patient safety initiatives with MDPH, the MA Hospital Association (MHA), The Betsy Lehman Center for Patient Safety and Medical Error Reduction, Massachusetts Senior Care Association, and Masspro (the Massachusetts QIO). The Coalition is currently actively engaged in the Partnership CDI Prevention Collaborative for hospitals and LTCFs.

Infection prevention (IP) work in Massachusetts is enhanced by relationships with a variety of academic experts in the state. Most recently, ID and pharmacy specialists from the University of Massachusetts Medical School, Brigham and Women's Hospital and Tufts Medical Center joined the MDPH and Coalition in planning and executing a statewide Antibiotic Stewardship workshop for almost 200 participants from more than 45 facilities.

Finally, active participation in CDC sponsored IP work has led us to develop valuable working relationships with the CDC staff and individuals in other states who are involved in CDC sponsored work. Dr. Arjun Srinivasin joined our team for a set of antibiotic stewardship calls, and Dr. Nimalie Stone has been invaluable in connecting us with people across the country with expertise in long term care IP and antibiotic stewardship. The work laid out in this proposal has been informed by the experience of colleagues in other states; relationships developed through participation in CDC sponsored initiatives.

Leveraging partnership initiatives

Through ongoing improvement work in Massachusetts many hospitals have developed collaborative relationships with partner LTCFs. Seventy five percent of hospitals in Massachusetts are involved in the Institute for Healthcare Improvement I sponsored STAAR project (State Action on Avoidable Rehospitalizations) with leadership and coordination by the Coalition, MHA, and MDPH. Acute care hospitals and LTCFs are actively improving a number of practices including practices to improve care coordination and reduce readmissions including patient assessment on admission, effective teaching and learning for the patient and supporting caregivers, appropriate handoffs to the next providers of care, and effective post-acute care.

Most recently, the Coalition has joined MDPH in an effort to improve IP practices in LTCF by creating clusters of acute care hospitals and LTCF (with ELC-ACA funding). These relationships will leverage the expertise on IP, microbiology and environmental services, among others hospital staff. Many of these hospitals participated in our ARRA funded CDI Prevention Collaborative. In the first two weeks of recruiting, over a dozen hospitals have signed on this Partnership Collaborative, and many others are discussing it with their hospital leadership.

The ongoing Partnership Collaborative offers advantages for the proposed antibiotic stewardship work. First we will enjoy greater impact, and some cost savings by avoiding new recruitment for the antibiotic stewardship collaborative. Second, the current work provides the base for us to address the three principal strategies CDC has identified as the foundation for reducing the threat posed by antimicrobial resistance in healthcare facilities; prevent the transmission of multidrug-resistant organisms (MDROs), prevent infections, and reduce unnecessary use of antimicrobials. Our current Partnership CDI Prevention learning collaborative will have prepared participating LTCFs for the work of antibiotic stewardship in part by supporting a culture of improvement with a focus on implementing best practices and using ongoing measurement to track the impact of new processes over time. Additionally, they will already be implementing changes to address the prevention of infections and the transmission of MDROs.

Expertise in key areas

The team assembled for this work offers valuable expertise in content areas as well as successful experience in conducting quality improvement collaborative and other methods to change practice and provider behavior. Our expertise detailed below will be augmented by an expert steering committee. We currently have agreements to participate from Dr. Ruth Kandel, MD (Assistant Professor, Harvard Medical School and Infection Control Director, Hebrew Senior Life), and Al DeMaria, MD (Medical Director, BID, and State Epidemiologist, MDPH).

Running successful learning collaborative

The Coalition and MDPH have collaborated on numerous improvement collaboratives. Two such initiatives successfully engaged 90% of hospitals statewide in improving medication reconciliation and communication of critical test results (2002-2005). From 2007-2009, Paula Griswold and Susanne Salem-Schatz led the Coalition's Infection Prevention educational programs – with 100% commitment by acute care hospital leadership for participation. Currently 67 hospitals are engaged in one or more of our improvement collaboratives.

Most recently we are recruiting for our new Partnership CDI Prevention Collaborative (partnering acute care hospitals with LTCF partners). We are also in the final months of an ARRA supported learning collaborative to prevent hospital-acquired *C. difficile* infection (HA-CDI). With a 27% reduction in HA-CDI per 10,000 patient days to date, we hope to exceed our goal (30%) among the 28 participating hospitals. Additionally, Collaborative Program Director, Susanne Salem-Schatz, ScD, brings over a decade of experience serving as director and improvement advisor in dozens of learning collaboratives on a variety of health care topics.

Quality improvement in LTCFs

The Massachusetts Senior Care Association engages their member organizations in numerous quality improvement initiatives. Some of these include:

- A leadership role in Advancing Excellence, a nationwide campaign to improve the quality of care for LTCF residents. Sixty per cent of the state's nursing facilities have signed on to the campaign, agreeing to pursue and track at least three quality improvement goals including at least one clinical and one organizational goal.

- Leading the INTERACT program (Interventions to Reduce Acute Care Transfers) to improve care transitions from hospital to nursing facility and nursing facility to home.
- Active partnership in the Institute for Healthcare Improvement's (IHI)'s STAAR program (detailed above). Many skilled nursing facilities are currently participating on these cross continuum care teams, and Mass Senior Care is a key partner in promoting effective coordination across the continuum of care.

Antibiotic Stewardship

Over the past year, we have included programming on antibiotic stewardship for hospitals participating in the CDI prevention collaborative. Ken Lawrence, PharmD (Tufts Medical Center), Lisa Davidson, MD (Tufts Medical Center), and Arjun Srinivasin, MD (CDC) have served as faculty on a series of conference calls. The recent MDPH / Coalition Antibiotic Stewardship Workshop, with assigned pre-conference readings and audio-conference, drew almost 200 participants including.

Antibiotic Use in Long Term Care

Through previous work and networking facilitated by the CDC, partners have been identified for this work with extensive experience. Dr. Shira Doron (ID Specialist, Tufts Medical Center) has experience working as a stewardship consultant to a LTCF. Laurie Herndon, MSN (MA Senior Care Foundation), a geriatric nurse practitioner, adds the combined experience of an educator and long term care prescriber. Lori Grubb, PharmD, brings the experience of a pharmacy consultant in long term care. Finally, Gail Bennett RN, MSN, CIC adds years of teaching experience in all areas of IP of long term care including antibiotic stewardship. She will be a trusted source of information for LTCF staff and, along with Ms. Herndon, adds the essential perspective of the role of nursing in LTCF antibiotic prescribing.

Organization development strategies form front line engagement and empowerment

Sharon Benjamin, Ph.D has been a member of our IP collaborative faculty for over three years. Her expertise in innovative approaches to front line engagement for quality improvement (such as Positive Deviance) have led to more effective engagement of front line staff in the work of the collaborative.

Strategies for changing physician behavior including prescribing

Prior to her consulting practice in quality improvement and program evaluation, Collaborative Director, Susanne Salem-Schatz, ScD., held research positions in academic institutions and health care delivery systems with a focus on strategies for changing provider behavior. She participated in a randomized trial of an educational outreach program (Academic Detailing) to reduce the use of anti-psychotic medications in LTCFs. She participated in a controlled trial of educational outreach to improve blood transfusion practice, leading work to understand the influences of clinical and non-clinical influences of physician behavior change.

We are confident that the combination of our partner relationships and our experience in developing and supporting IP collaboratives, augmented by expertise in organizational learning, prescribing in long term care, and physician behavior change place us in an excellent position to design and lead the work laid out as Activity B in the current proposal.

b) Operational Plan

Below is an outline of the proposed program elements.

Collaboration

- Collaborate closely with key stakeholders.
- Target participants in our Partnership CDI Prevention Collaborative who have already developed collaborative working relationships between acute care hospitals and LTCFs.

Content and Curriculum

- Work with experts in ID, pharmacy, microbiology, and IP to develop a curriculum tailored for LTCFs, and their partner hospitals, with an additional focus on asymptomatic bacteriuria.
- Offer expert face-to-face training on principles of antibiotic stewardship through face-to-face meetings, site visits and conference calls.
- Target inter-facility communication and collaboration between hospitals and LTCFs to ensure information essential for antibiotic stewardship is included when patients are transferred, and increase skills and coordination in stewardship.

Innovative practice improvement methods

- Apply innovative strategies for front line engagement, provider behavior change, and practice improvement.
- Provide “train the trainer” slides and tools for use by participants in their home facilities.

Measurement

- Offer technical support to facilities interested in implementing NHSN *C. difficile* or antibiotic use modules.
- Create measures based on NHSN definitions including ongoing measures for improvement to be tracked by participating facilities.
- Create measures and conduct analyses to document program effectiveness.

Dissemination/Spread

- Post strategies, tools, and other resources on the MDPH and Coalition website to share broadly beyond the Collaborative members.
- Provide the final content of the transfer form to the Massachusetts HIT pilot of an electronic transfer form.

LEVERAGE COLLABORATIVE RELATIONSHIPS

Core partners in this work include the MA Coalition for the Prevention of Medical Errors, MA Senior Care Foundation, and Masspro (the Massachusetts QIO). We are purposefully coordinating the numerous improvement initiatives in which many Massachusetts facilities are participating. Our goal is to leverage these opportunities, and to avoid unnecessary effort or conflicts for program participants. Relationships previously developed with clinical experts in infection prevention and antibiotic stewardship ensures that our program will have optimal clinical content and the support of respected professionals.

By focusing participation in the proposed project on those facilities engaged in our current Partnership CDI Prevention Collaborative, we begin with a base of trust and respect between

acute care hospitals and LTCFs, facility based teams with a foundation in IP and quality improvement, and energized participants who value the expertise and support they received from experts and their colleagues in the prior collaborative.

CDC sponsored networking opportunities also have led to relationships with other states already engaged in long term care infection prevention and antibiotic stewardships. Conversations and shared materials with colleagues in CA, NY, PA, TX and VT have already and will continue to provide valuable lessons from their experience. This number will expand and we look forward to sharing our experience and materials with other states in the future.

CONTENT AND CURRICULUM DEVELOPMENT

Through our ARRA funded Hospital CDI Prevention Collaborative we have developed relationships with 28 hospital teams who have made remarkable progress in IP practices and the reduction of HA-CDI. We will call on these teams including individuals in IP, quality, microbiology, and environmental services to review and contribute to our curriculum as well as share their lessons with participants in the proposed collaborative.

Working closely with experts in ID, pharmacy, microbiology, and IP we will develop a curriculum tailored for LTCFs with an additional focus on asymptomatic bacteriuria. We will survey CDC-funded partners and colleagues in other states to identify existing content and tools, such as the ASP developed by Dr. David Calfee and colleagues at with the Greater NY Hospital Association in partnership with the United Hospital Fund, or the form developed by Charles Phillips at Texas A&M to guide conversations between LTCF nurses and prescribing providers and promote appropriate prescribing in the treatment of UTIs.

We will work further with our team to refine the curriculum; our current curriculum priorities are outlined below.

1. Improve communication about antibiotic use at the time of transfer

Building on our work to prevent hospital readmissions we will develop, test, and refine a standardized communication template to be used by hospitals when discharging a patient to a LTCF, and by LTCFs when transferring patients to acute care hospitals. This template will include required fields such as culture history (including susceptibilities) and antibiotic history. Acute care hospitals will include, the indication and the start date of each, the planned stop date of each, whether an ID Physician was involved in the antibiotic plan, and whether a follow-up appointment for the infection by a specialist is recommended for all patients on antimicrobials.. The template will also include a phone number of a physician at the acute care facility who can be contacted with questions about the antibiotics and treatment of the infection. We will leverage our connections to the national STAAR and INTERACT programs to identify similar forms currently in use elsewhere, and the strategies that create the most effective communication and coordination when transfers occur.

2. Promote appropriate antibiotic use and review of duration

Implementation of the communication tool described above, and education for long term care clinicians in antibiotic stewardship, will facilitate the ability of the receiving facility to make

appropriate decisions regarding the antibiotics choice and duration. To support optimal antibiotic use we will encourage both hospitals and LTCFs to test and implement a policy requiring every antibiotic order to have an indication and an end date, plus a practice of an “antibiotic time-out” at 72 hours to check culture data and de-escalate when appropriate.

3. Appropriate diagnosis and treatment of Urinary Tract Infection

Research on the challenges associated with the difficulty of diagnosing UTI in the long term setting and the frequency of inappropriate use of antibiotics for this condition make it a high leverage area to target practice improvements. We will identify or develop a clinical pathway that will encompass most of the common scenarios related to the diagnosis and treatment of UTI. "Train the trainer" education sessions will be held with nursing and physician leadership and nurse educators from the participating LTCFs and acute care hospitals, who will then be encouraged to educate staff at their facility.

The integral role of nursing in long term care offers a unique opportunity to engage nursing in promoting optimal testing and prescribing. To support adherence to the clinical pathway, we will develop a standardized communication template to enhance communication between nurses and physician to facilitate appropriate evaluation and management of UTI. The template will include questions about symptoms, the reason for the urinalysis/urine culture, a prompt to send both a urinalysis and urine culture to the laboratory, and reminder to check urinalysis results the same day if empiric antibiotics are being started, and culture results every day for three days until finalized. If empiric antibiotics are being started, the form will prompt the nurse to discuss with the physician all prior culture results available for that patient and all antibiotic courses given in the prior two months, as well as allergies.

A second section of this communication form to be completed once urinalysis results are obtained, will remind the nurse to discuss with the physician the need to discontinue antibiotics if urinalysis is not consistent with UTI. A second page of the communication form, to be filled out on day two or three after the specimen was sent will include a prompt to inform the physician of the culture results, compare the antibiotic with the susceptibility results, ask the physician if there is a narrower spectrum antibiotic that can be used in place of that which was started empirically, and ask what duration of antibiotics is appropriate for this infection (with prompts that provide appropriate durations for the various types of UTIs).

4. Laboratory practices: testing policies and the value of antibiograms to make appropriate antibiotic choices.

We will offer guidance to frontline staff and prescribers in LTCFs in communicating with their laboratory to understand their processes, such as how to interpret urinalysis and urine culture results and susceptibility reports. Laboratories serving participating LTCFs will be encouraged to produce annual antibiograms for LTCFs. Today, issues related to changing susceptibility breakpoints and planned FDA modifications to existing laboratory guidelines make interpretation of antibiotic susceptibility data exceedingly complicated, particularly when dealing with the more resistant bacteria.

We will leverage our collaborative's acute care hospital /LTCF partnerships and encourage hospital microbiologists to mentor reference laboratories, when needed, regarding the interpretation of susceptibility data on MDROs so that clinicians at the LTCF can properly interpret such data to make appropriate antibiotic choices for MDRO infections, thus avoiding unnecessary transfer to acute care due to antibiotic failure and subsequent worsening infection.

INNOVATIVE PRACTICE IMPROVEMENT METHODS

The methodology for this work will be an augmented learning collaborative building on hospital /LTCF partnerships developed through our current Partnership CDI Prevention Collaborative. In addition to topic specific learning events, we will employ innovative strategies to support front line engagement such as training and real-time practice using action research, simple ethnography tools that provide the opportunity for learning about behaviors through skilled observation, and Positive Deviance among other emergent strategies.

Key features of Academic Detailing will also be employed, such as background assessment of provider motivation for current prescribing practice and barriers to change, and the preparation of graphically appealing information and tools to support desired changes in practice. We will also emphasize a "Train the trainer" approach, and provide workshop participants with slides and exercises to use with staff in their home facilities.

As in many programs based on a learning collaborative, participating teams will be multidisciplinary. We will also emphasize the use of program theory and quality improvement techniques. We will create opportunities for shared learning to supplement expert presentations. Encouraging teams to establish aims, monitor measures for improvement and use small tests of change prior to facility wide- implementation may no longer be considered "innovative," but are the foundation on which successful of improvement initiatives are built.

- Advisory group representing hospital and long term care providers: physicians, nurse practitioners, nursing, pharmacy, infection control, microbiology and ID physicians.
- Acute care hospital / LTCF Partnerships
- Needs assessment:
 - survey of LTCF antibiotic stewardship practices at baseline
 - key informant interviews to evaluate determinants of prescribing
- Two central learning sessions (June, November), the last of which will be extended statewide to share strategies for success. (a February learning session is already included in the current Partnership Collaborative)
 - Expert content
 - Opportunities for shared learning among peers
 - Exercises to promote front line engagement
 - Train the trainer approach through modeling behavior and provision of training materials and tools
 - Coaching for spread and sustainability
- Six coaching and shared learning conference calls

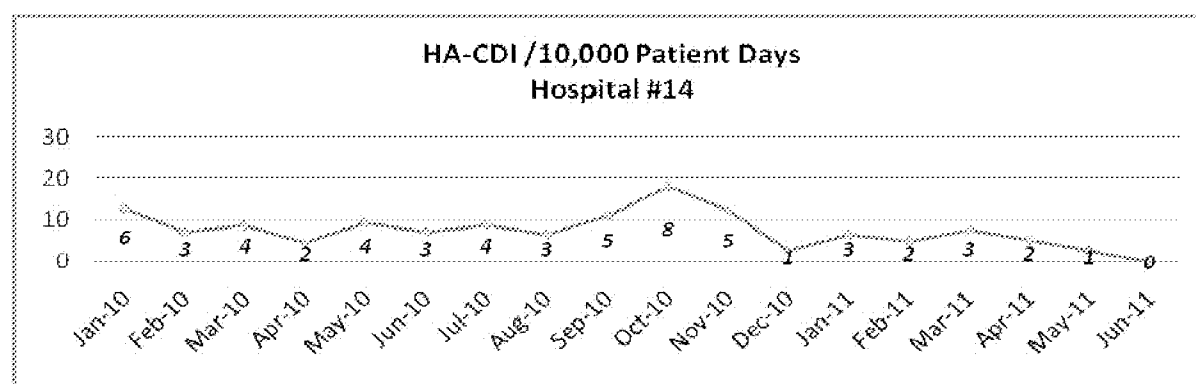
- Measurement (using NHSN definitions) for improvement and to demonstrate program effectiveness

MEASUREMENT FOR IMPROVEMENT AND TO DEMONSTRATE PROGRAM EFFECTIVENESS

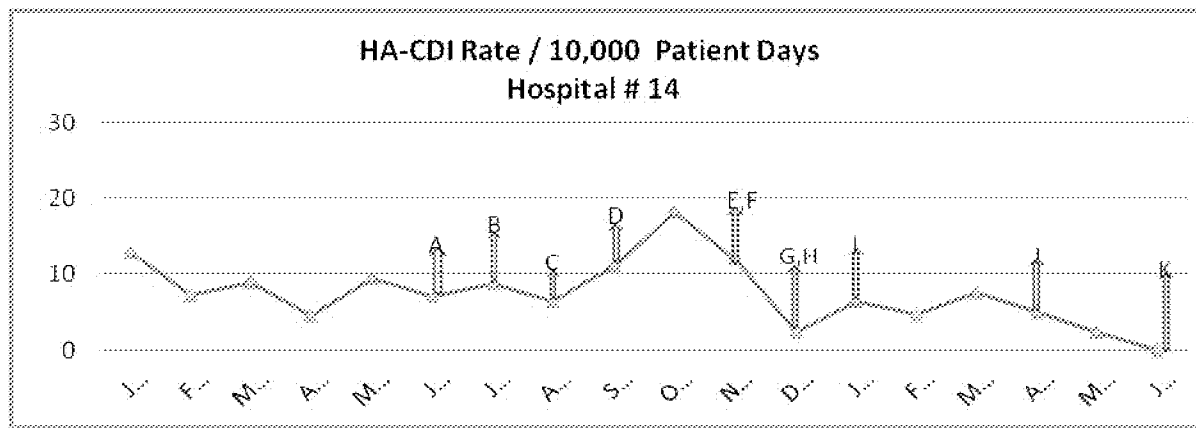
Documenting antibiotic use and *C. difficile* infection in Long Term Care

We will work with participating LTCFs to establish a system for tracking facility-level antibiotic use utilizing the methodology described in the NHSN CDI and Antimicrobial Use and Resistance Module and report facility wide CDI utilizing the CDC-NHSN lab ID definition. We will assess the capability for implementation of the NHSN CDI and Antimicrobial Use and Resistance Modules in collaborative participants with advanced information system capability. MDPH will provide technical assistance to LTCFs who have the capacity and interest in implementing NHSN modules. Based on conversations with states attempting to implement NHSN inmLTCF, we propose a back-up method so we can begin to measure on day one.

In our current CDI Prevention Collaborative, we created Excel templates into which participating hospitals entered their HA-CDI cases (according to NHSN criteria with which they were provided) and patient days on a monthly basis. This automatically created a run chart so the teams could monitor progress over time (see example below). While we have not audited these numbers, we are confident that the approaches used by each hospital are consistent over time and allow them to accurately track their improvement. Over 95% of Collaborative hospitals have submitted complete monthly data beginning in January 2010.



We also have encouraged hospitals to create annotated run charts to show how improvement activities relate to changes in outcomes over time.



Key to above chart

- A. Attend CDI Prevention Collaborative Kickoff Meeting
- B. Launch antibiotic stewardship committee
- C. Restrict use of Quinalones
- D. Reinforce use of bleach in cleaning and change bedside curtains at discharge for patients with CDI
- E. Host Regional Collaborative Workshop
- F. Implement "Dear Doctor" letter for patients with CDI
- G. Continue work with Pharmacy and Infectious Disease on prudent use of antibiotics through antibiotic stewardship committee
- H. Reinforce hand hygiene with soap and water in addition to the hand sanitizer
- I. Transition to new infection preventionist
- J. Surveillance screening protocols for patients are automatic upon admission
- K. *C. diff* DNA testing by illumigene NAA (nucleic acid amplification) method

Activity 1: *Develop and implement a multi-site antibiotic stewardship collaborative in the setting of long term care.*

Year 1 (1/1/12-12/31/12) Program staff will:

- Convene a multidisciplinary advisory committee.
- Develop strategic planning for antibiotic stewardship program.
- Provide ongoing review and evaluation of collaborative process.
- Design and conduct a LTCF antibiotic stewardship needs assessment.
- Develop an antibiotic stewardship curriculum; design initial tools to support change and educate clinicians and staff.
- Evaluate capacity for surveillance and measurement in LTCFs and support development of systems to document antibiotic use.
- Conduct two full day LTCF/ hospital partnership learning sessions.
- Conduct four learning and sharing conference calls.
- Provide support for implementation of NHSN as requested.
- Collect, review and analyze monthly data reports using NHSN definition for Lab-Id events.
- Collect and provide analysis for data on LTCF hospital transfers.

- Disseminate tools and materials developed on MDPH and the Coalition websites, as requested by additional state health departments and CDC.
- Ensure effective coordination and collaboration with the IMPACT project.
- Produce final content of the antibiotic stewardship transfer form to incorporate in the IMPACT project electronic transfer form.
- Create a policy brief for the CDC summarizing strategies; potential challenges and recommendations facilitate the spread of antibiotic stewardship programs.

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5, antibiotic stewardship will remain be an integral component of HAI prevention program initiatives.

Objective/Activities	Timeframe	Staff Responsible
Launch advisory committee	1/12	Collaborative leaders, HAI Coordinator, State Epidemiologist
Strategic planning for antibiotic stewardship collaborative	1/12	Collaborative leaders, HAI Coordinator,; Advisory Committee, ID physician, pharmacist, organizational development consultant
Design and conduct LTCF antibiotic stewardship needs assessment	1/12-2/12	Collaborative leaders, HAI Coordinator, ID Physician, pharmacist, Long term care (LTC) IP, epidemiologist
Develop antibiotic stewardship curriculum	1/12-2/12	Collaborative leaders , Advisory committee, ID physician, pharmacist, LTC IP
Design initial tools to support change and educate clinicians and staff.	2/12	Collaborative leaders, ID physician, pharmacist, Advisory committee
Evaluate measurement and surveillance capacity in LTCFs; Support development of systems to document antibiotic use.	2/12-3/12	Collaborative leaders Coalition, MDPH, epidemiologist
Conduct full day LTCF/Hospital partnership learning sessions	6/12, 10/12	Collaborative leaders ID physician, pharmacist, .HAI Coordinator; Advisory committee, ID physician, pharmacist, LTC IP
Conduct four learning and sharing conference calls	2/12 through 12/12	Collaborative leaders, ID physician, Coordinator; Advisory committee, ID physician, pharmacist, LTC IP, microbiologist, organizational development consultant
Support implementation of NHSN as requested	3/12- 5/12	MA MDPH
Collect, review and analyze monthly data reports using NHSN def. for Lab-ID events	2/12 through 12/12	Collaborative leaders , epidemiologist
On-going review and evaluation of collaborative progress	1/12 and ongoing	Collaborative leaders , Coordinator HAI Technical Advisory Group
Collect and analyze LTCF hospital transfers	1/12-12/12	Collaborative leaders, MDPH, Statistician
Post materials developed in the Collaborative on MDPH and Coalition website	5/12-12/12	MDPH, Collaborative leaders
Collaborate with IMPACT project; provide final content for stewardship transfer form to incorporate in electronic transfer form	1/12-12/12	Collaborative leaders

c) *Measures of Effectiveness/Measurable Goals*

The following table lists the process and outcome measures proposed for use in the Antibiotic Stewardship Learning Collaborative. We also propose to track obstacles faced in implementing ASPs in LTCFs, which may include payment and regulatory requirements, and the strategies we develop to overcome them or proposed changes that would support antibiotic stewardship. We will create a policy brief for the CDC to summarize these challenges and strategies, along with recommendations to facilitate the spread of similar programs.

Table of Process and Outcome Measures			
Measure	Definition	Numerator	Denominator
PROCESS MEASURES			
Collaborative Participation	Number of facilities engaged in collaborative to develop stewardship interventions	# of participating facilities # Participating teams attending 80% or more events	NA Total # teams
Degree of engagement	Percentage of hospitals and LTCFs participating in collaborative events and meeting collaborative expectations	Number of LTC facilities participating in 80% or more collaborative activities (attend meetings, testing, etc)	Number of LTC facilities
Status of surveillance of antimicrobial use	Percentage of collaborative partners that have implemented a standard surveillance mechanism, utilized by all collaborative facilities, to monitor all antimicrobial use.	# participants implementing standard antimicrobial use surveillance mechanism	Total # teams
Description of facility – based stewardship interventions	Number and type of antimicrobial stewardship interventions implemented in collaborative facilities Percentage of facilities implementing each core stewardship strategy	Average number of interventions Range of number of interventions # implementing each strategy	NA Total # facilities
Infection prevention practice performance	Results of Baseline Stewardship Practice Assessment Tool. (To be completed at baseline and again at end of program.)	Number of LTC facilities with core features	Number of LTC facilities
OUTCOME MEASURES			
Decreased use of antimicrobials.	Percentage reduction in total antimicrobial use in collaborative facilities Percentage reduction in antimicrobial use for treatment of UTI in collaborative facilities		
Increased appropriateness of prescribing for UTIs	Percentage of completed UTI templates demonstrating appropriate antibiotic usage.		
Change in CDI Rate in LTCFs	Comparison of health care acquired CDI rates in LTC facilities during baseline and	CDI cases per the NHSN lab ID	10,000 resident/patient

	program periods - Hospital Acquired, Other Health Care Facility, and Community Acquired	definition	days
Change in Acute Care Hospital CDI Rates	Comparison of CDI rates in Collaborative Hospitals during baseline and program periods: disaggregated by Hospital Acquired, Other Health Care Facility, and Community Acquired.	CDI cases per the NHSN lab ID definition	10,000 patient days
Avoided hospital admissions from LTC	Change over time in admissions to all hospitals with diagnosis of CDI or sequellae of CDI (codes to be determined)	LTCF documentation of admissions to all hospitals with CDI dx or other specific codes	LTC Resident days during time periods
LTC-Acquired CDI Burden within Collaborative partners	Change over time in patients admitted to participating hospitals from partner LTCFs with diagnosis of CDI or sequellae of CDI (codes to be determined)	Admissions to participating hospitals from partner LTCFs with any CDI dx or other specified codes	LTC Resident days during time periods

Finally, the MDPH and the Collaborative leader will post on its public website the strategies, tools, and other resources developed by the project faculty, and revised based on the experience of the Collaborative participants, in order to share these resources broadly beyond the Collaborative members.

Through partnership with another ongoing pilot project in the state (known as IMPACT – Improving MA Post Acute Care Transitions), the implementation of an electronic transfer from across the continuum of care providers in the Worcester, MA area, we can also increase the impact of the project. The IMPACT project is a federally funded HIT pilot, with involvement of the MDPH, and collaboration with the MA Coalition for the Prevention of Medical Errors and the STAAR project, to provide electronic communication to support care transitions. The content we develop addressing antibiotic stewardship will be provided to project leaders in IMPACT, for incorporation in the final electronic transfer from.

E. Identify cost-effective and evidence-based HAI intervention strategies

a) Background, Need and Understanding

The effects of preventable healthcare associated infections (HAIs) on patients and families, and the associated cost to the healthcare system, remain a prominent national healthcare issue. Recent widespread attention from the public, the healthcare industry, state and federal policy makers has resulted in greater focus on improving the quality and safety of healthcare including the expansion of initiatives to address HAI. While much of the effort committed to the elimination of HAIs has been aimed at prevention, the importance of evaluating the effectiveness of current prevention initiatives is recognized.

The purpose of this proposal is to evaluate efforts that support, maintain, and enhance statewide efforts to reach HAI prevention goals as outlined in the *HHS Action Plan to Prevent Healthcare-Associated Infections* and the MA HAI Prevention Five Year Plan. Specifically, this application seeks to evaluate the efficiency and efficacy of interventions undertaken by The MA Coalition

for the Prevention of Medical Errors which has been working under contract to the Massachusetts Department of Public Health (MDPH) to implement an ARRA funded *C. difficile* Infection (CDI) Prevention Collaborative to build and sustain state programs to prevent HAI infections. Now is a good time to conduct an evaluation of these interventions as MDPH was recently awarded funds to extend this collaborative to include long term care facilities (LTCFs) with ELC-ACA funding.

The purpose of this project will be to identify implementation strategies with the greatest efficiency and simplicity, along with cost-savings associated with implementation in the prevention of healthcare acquired *C. difficile*. The implementation project being proposed for evaluation will be conducted in an estimated 18 healthcare acute care facilities, with each acute care facility partnering with approximately three LTCF that do not provide acute care. Thus, the total number of participating facilities is estimated to be approximately 54 combining acute care and long-term care organizations.

The focus of this evaluation will be to:

- 1) Identify strategies that have improved the implementation of and adherence to existing prevention recommendations for HAI, e.g. those associated with CDI, hand hygiene, and contact isolation.
- 2) Evaluate these implementation strategies to determine efficiency, simplicity, and cost.
- 3) Conduct appropriate surveillance and assessment to demonstrate effectiveness of interventions
- 4) Assess the impact of the prevention strategies including outcomes such as hospitalization

This evaluation will support the rollout of strategies for reducing incidence of CDI in acute and non-acute healthcare settings, as well as informing future measurement and quality collaborations.

Implementation Project Being Evaluated

With ARRA support from MDPH, the Massachusetts Coalition for the Prevention of Medical Errors is in the final months of a learning collaborative to prevent hospital acquired *C. difficile* infection (CDI). With a 27% reduction to date, we hope to exceed our goal of a 30% reduction among the 27 participating hospitals. Core features of the original project include: multidisciplinary teams with representatives from infection prevention (IP), quality, clinical leadership, microbiology, pharmacy and environmental services; a common set of practice recommendations in the areas of surveillance testing, isolation policies, hand hygiene, contact precautions, and environmental cleaning and disinfection; three statewide full day learning and sharing workshops featuring expert presentations and highlighting accomplishments of collaborative participants. Significant emphasis has been placed on teaching and using Positive Deviance, Liberating Structures and other innovative organizational change techniques based on emergence, regional workshops featuring strategies for front-line staff engagement, common measurement and reporting tools based on NHSN HAI definitions, support for teams working on antibiotic stewardship including conference calls and a full day workshop.

MDPH has received ACA funding through July 2012 to engage participating hospitals in partnering with LTCF to co-create strategies for reducing CDI. The additional resources will allow expansion of CDI prevention efforts to the long term care setting. The project is designed to create partnerships between hospitals and nearby LTCF where all of the participating organizations are working to eliminate CDI. The partnerships implement optimal prevention practices in these areas, promote understanding of risk factors for CDI, develop guidelines and options for microbiological testing, isolation policies, hand hygiene, contact precautions and transition planning and guide communication between hospitals and long-term care as patients are transferred from one setting to the other.

We have little information about current CDI prevention practices in LTCFs and are therefore are not predetermining specific numerical targets for decreased CDI over the project term until we can collect and assess baseline data from participating LTCFs. The methodology for the implementation project is an augmented learning collaborative, which links hospitals with the LTCF where they frequently refer. Implementation project timelines, milestones and target dates are outlined below side by side with the proposed evaluation activities and dates.

Recruitment for Participation in Implementation Project

Participants in the overall project have been recruited through the existing CDI Prevention collaborative and in the STAAR initiative as these facilities can leverage both their expertise and strategies for CDI prevention, as well as relationships developed with key referring LTCF. A single email describing the potential for this work yielded 13 replies from hospitals. We expect to enroll up to 18 hospitals with two to three LTCFs partnering with each hospital.

Need for Evaluation

The success and expansion of the implementation project referenced in this evaluation proposal make this a critically important time to undertake formative evaluation activities. Participants in the current project will benefit from attaining a better understanding of what works and what does not. Further, future intervention projects can be informed by the lessons learned to date. The evaluation proposed here of the project's implementation activities and their impact is based on similar methodological guidelines consistent with the design of quasi-experimental studies. Qualitative assessment of project activities will be conducted at the beginning of the project in January 2012 providing baseline data and, pending funding, upon completion of the project in December 2012. Participating hospitals and LTCFs will be assessed using standard measures across all three evaluation activities (outlined below). These measures will be informed by the quantitative clinical data being gathered during the course of the actual intervention project. (See the appendices for a full set of the outcome measures being used for the project.)

b) Operational Plan

We propose a qualitative evaluation, based primarily on three major activities.

- 1) **Social Network Analysis** of selected participating facilities pre and post intervention will be conducted in order to assess changes in the social connections between participants in selected participating organizations over the course of the project;

- 2) **Interviews with selected participants** will be held at two points in the project (midway and post). The value of these interviews will be in eliciting honest and iterative input from program stakeholders; we will rely on a combination of individual interviews conducted by phone and group interviews conducted in person.
- 3) **Self-report survey data** on the initiative will be requested of all project participants via an on-line survey tool.

Evaluation Methods

Our evaluation approach is both formative and collaborative. In assembling the evaluation team we will seek individuals with diverse training and experience (clinical, management, social science and academic) but similar world views and shared vocabulary to maximize the potential for discovery and insight across disciplines, while providing for shared exploration and analysis. The guiding principles here are to undertake an inductive inquiry without a predetermined hypothesis. Equally important, we seek practical application of qualitative methods that simply involve asking open-ended questions of people and observing matters of interest in real world settings in order to solve problems, improve programs or develop policies.

Initial Planning and On-going Synchronization within Project Team

This evaluation is conceptualized as a wide net designed to capture discrete, concrete evidence and identify patterns across facilities; this will require good communication among the members of the team. The evaluation team will initially meet at the outset of the project to review evaluation goals, collateral, process and make any necessary changes. We will conduct periodic evaluation team calls, we will prepare and distribute progress notes and seek input regarding changes in approach or interview guides that might be appropriate as a result of new insights that emerge or unanticipated events as the project develops.

Tools

1) Social Network Mapping and Analysis

Commercially available electronic social network mapping and analysis tools such as software developed by the Plexus Institute or Johns Hopkins will provide the mechanism for conducting an assessment of communication, participation and teamwork among participants. Social network analysis has been used to reveal the communicative patterns of complex groups and teams in order to identify 1) the strength and frequency of the connections between members, 2) the level of knowledge members have concerning the structure of the network, and 3) the evaluation by members concerning the overall success of the network.

- Social Network Analysis (SNA) is a visual and mathematical analysis of how people interact, exchange information, learn and influence one another.
- SNAs make invisible structures visible -- uncovering communities, key players, opportunities and vulnerabilities in the network.
- SNAs are conversation starters. They show the current state, but do not define success or the best strategies for implementing improvements.

Using this type of tool has significant advantages in that other IP collaboratives in the US and Canada have used these tools with regard to similar initiatives designed to prevent hospital

acquired MRSA infections thus providing a solid foundation for assessing results from this inquiry. The social network maps that resulted from these investigations have proven to be useful learning and engagement tools as well as provide a powerful lens for understanding how an intervention is influencing actual behaviors of individuals.

Knowing that groups and teams benefit from a diverse membership, successful networks encourage open communication between a variety of units and roles. The success of the first phase of the CDI collaborative has prompted our curiosity about the connectivity of the social networks responsible.

Methodologically, we will gather baseline data from project participants in January, 2012, in the form of a survey questionnaire, to reveal the overall connectivity of the initial social network at baseline (before implementation). A sample of the survey questions are: 1) "With whom do you work on CDI efforts?" 2) "Over the past 12 months, from whom have you gotten new ideas or inspiration that helped you in your CDI reduction efforts?" 3) "List projects and activities and people you have worked with on those projects." 4) "Who would you like to work with during the coming year on CDI reduction efforts?" Upon funding, subsequent social network analysis will be conducted with selected participants in order to help assess whether the project has had an impact and, if so, in what ways the social networks have changed. This survey will be conducted at the end of the grant period in December, 2012.

2) Individual and Group Interviews: Interviewers and Guides

This evaluation builds on several earlier explorations and evaluations of emergent interventions such as Positive Deviance and Liberating Structures conducted by the Maryland Patient Safety Center, Plexus Institute and the Regenstreif Institute. In order to continue to build coherence and understanding, we recommend using the interview guide developed by the Regenstreif Institute and Plexus Institute research team in the spring of 2010 (see appendix). This interview guide was extensively critiqued and field tested before its adoption as the qualitative interview guide for the CDC-funded MRSA prevention initiative run by Regenstreif Institute.

This evaluation will focus on concrete examples of shifts in behavior and performance as observed by healthcare facility staff. Specifically, we will seek small, often unnoticed changes that have significant ripple effects in the effectiveness and efficiency of clinical practice. We will pay attention to four dimensions, known to be critical for successful progression from program inputs to desired outcomes. In addition to guiding the interview development, this approach will generalize our findings to future initiatives.

Dimension	Topic			
	Project management / logistics	Politics	Technical issues	Sustainability
People				
Process				
Communication / information				
Resources				

Confidentiality - During interviews, interviewers will inquire about participants' willingness to talk about sensitive issues and offer not to attribute comments if desired by the respondents. In some cases it may be difficult to ensure anonymity, especially among stakeholder groups with limited representation, but this will be discussed and resolved with participants.

Data Collection - We will conduct phone interviews at the convenience of the selected participants, including early morning or late evenings as necessary. Interviews will be designed to take 60 minutes and capped at 90 minutes. Interviewers will record phone and in-person interviews and will also take notes by hand. Audio recordings will be available as needed.

Analysis - Notes from telephone interviews and survey results provide the primary data for analysis. Telephone interviews will be analyzed with qualitative data analysis, coded for key words, critical incidents, patterns and themes, aggregated and summarized. Patterns and themes will be supported with illustrative quotes. Interviews will be triangulated and augmented with survey findings and our own observations. We will make preliminary recommendations based on our interpretation of findings.

Selection Criteria for Evaluation Activities (1) and (2)

Participant selection for activities (1) and (2) will be based on evaluators' assessments of two critical factors: potential and behavior. As this is a limited evaluation, the most time intensive evaluation activities will be focused on high-potential and high and possible medium activity participants. Work with emergent organizational behavior change suggests that these changes are often difficult to identify without concerted, concentrated questions. Hospitals working to reduce MRSA frequently do not appear to "be doing much" but upon deeper probing profound and sweeping changes have resulted from seemingly small events.

3) Individual and Group Interviews: Interviewers and Guides

At the conclusion of the initiative, all participants will be asked to complete a short survey on their experiences participating in the overall CDI collaborative via an on-line survey tool. It is expected that questions of compelling interest to the full group will emerge over the course of the implementation project. Survey data will be collected in the spring of 2012 (midterm) and over the summer of 2012 upon completion of the CDI implementation project and results will be reported to collaborative participants in a variety of formats beginning in Fall, 2012. Evaluation activities will be complete by the end of December 2012.

To support this initiative, MDPH requests support for one FTE epidemiologist. The epidemiologist will function as an integral part of the HAI Program and will be trained on all HAI related issues, including surveillance, NHSN reporting, electronic transfer of data, identification and investigation of outbreaks, recognition of emerging pathogens and unsafe practices and assisting in the identification of prevention needs. In collaboration with HAI Coordinator and the evaluation team, the epidemiologist will aid in planning and management for the evaluation initiative including: assisting in selection of evaluation participants; development of survey tools and the methodology for data collection; and the development and analysis of pre and post intervention analysis tools. To increase inter-rater reliability, and provide for a consistent clinical voice, the epidemiologist will serve as a resource in all phone

interviews and in-person site-visits. The epidemiologist will also participate in the planned regional and statewide learning sessions, assist in the preparation of the final report and make the presentation of the final results.

We will prepare a final report of the findings and a final presentation of our results for use by participating facilities and other interested parties both within and outside of Massachusetts. We will use an iterative and collaborative approach in developing these materials and will include some feedback mechanism for participating healthcare facilities prior to finalization of the presentation.

b) Operational Plan

Activity 1: Conduct activities to evaluate the efficiency and efficacy of HAI prevention interventions implemented within the current multi-center CDI collaborative.

Evaluation staff will:

- Develop evaluation planning and management strategy.
- Prepare social network analysis (SNA) questionnaire.
- Conduct and participate in evaluation team calls.
- Select/recruit facilities to be included in evaluation.
- Participate in and observe regional learning workshops.
- Participate in and observe statewide training meetings.
- Conduct mid-intervention and post intervention phone interviews.
- Conduct post-intervention on-line survey with all participants.
- Conduct post-intervention site visits.
- Conduct analysis of data collected.
- Conduct three evaluation team meetings to discuss findings and identify patterns (if any). These meetings will be conducted via GoToMeeting.com or a similar technology.
- Provide a written analysis of interviews.
- Produce SNA maps.
- Present findings prepared based on interview analysis and SNA maps.
- Compile and deliver a final deliverable binder.

Year 1 (1/1/12 –12/31/12):

- Immediately upon grant award and ongoing through 12/31/12 we will develop team planning and management strategy.
- By 1/12 evaluation team will conduct analysis of social network analysis questionnaire.
- By 1/12 evaluation interview teams will participate in and observe regional learning workshops.
- By 2/1/12, epidemiologist position will be created and posted.
- By 3/1/12, epidemiologist will be hired.
- By 3/12, evaluation interview teams will participate in and observe statewide training meetings.

- By 4/12, evaluation interview teams will participate in and observe regional learning workshops.
- By 4/12 select/recruit facilities to be included in evaluation.
- By 4/12 and Fall/12 will conduct mid-intervention and post intervention phone interviews.
- By 9/12 will conduct on line survey with all participants.
- By 9/12 will conduct post intervention site visits.
- By 9/12 will conduct post intervention social network data collection.
- By 10/12 will conduct data analysis.
- By 12/12 will conduct three evaluation team meetings to discuss findings and identify patterns (if any).
- By 11/12 interview analysis written.
- By 11/12 SNA maps produced.
- By 12/12 Presentation of findings prepared based on interview analysis and SNA maps.
- By 12/12 Final deliverable binder compiled and disseminated.

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5, formal evaluation will be an integral part of HAI prevention program initiatives. The approach and methods will vary according to the specific project and the availability of resources

c) Measures of Effectiveness (1/1/12- 12/31/16)

Effectiveness will be measured by the number of acute and non-acute healthcare facilities that have had an evaluation of implemented prevention recommendations. MDPH will target at least four healthcare facilities (including at least two types of acute and non-acute healthcare settings) to evaluate and identify effective strategies.

Implementation project timelines, milestones and target dates are outlined below side by side with the proposed evaluation activities and dates.

CDI Prevention Project Objective/Activities	Timeframe	Proposed Evaluation Activity	Timeframe	Responsible Staff
Develop and implement new collaborative multicenter evidence-based HAI prevention initiative	9/1/11-9/30/12	Evaluation planning and management	Immediately upon grant award and ongoing through 12/31/12	Evaluation Team Epidemiologist HAI Coordinator
Strategic planning for CDI collaborative	Through 10/15/11	Evaluation team call(s)	Immediately upon grant award and on-going through 12/12	Evaluation Team Epidemiologist
Recruit approximately 24 acute care hospital teams	By 9/30/11			
Recruit approximately 72 LTCFs teams	By 10/21/11			

Develop change package (tools, slides, etc.)	By 10/31/11			
Conduct LTCF leadership conference call for partner organizations to introduce initiative and obtain commitment	Schedule 10/31			
Prewrite call for participating hospitals and LTCF	Schedule 10/11			
Facilitate and coordinate hospital team on-site visit to LTCF	10/11-11/15/11			
Administer, analyze and share results - CDC LTC baseline prevention practice assessment tool	Complete 11/11			
		Social network analysis questionnaire analysis	1/12	Evaluation Team Epidemiologist
		Select/recruit facilities to be included in evaluation	4/12	Evaluation Team Epidemiologist
Conduct four regional learning workshops	Scheduled – 1/12, 4/12	Evaluation interview teams to participate in and observe regional learning workshops	1/12 and 4/12	Evaluation Team Epidemiologist
Conduct two statewide infection prevention training workshops for staff from other LTCF	Scheduled 3/11 and 3/12	Evaluation interview teams to participate in and observe statewide training meetings	3/11 and 3/12	Evaluation Team Epidemiologist
Conduct full-day antibiotic stewardship workshop with conference calls in months before and after the meeting	Scheduled 1/12-4/12			
Collect, review and analyze monthly data reports using NHSN definition for Lab-ID events	10/11 and ongoing	Mid-intervention and post intervention phone interviews	4/12 and Fall/12	Evaluation Team Epidemiologist
On-going review and evaluation of collaborative progress	10/11 and ongoing	Conduct post-intervention on-line survey with all participants	7/12 to 9/12	Evaluation Team Epidemiologist
		Post-intervention site visits	7/12 to 9/12	Evaluation Team Epidemiologist
		Post-intervention Social Network Data collection	7/12 to 9/12	Evaluation Team
		Data analysis	8/12-12/12	Interview team members Epidemiologist
		three evaluation team	7/12-12/12	Evaluation Team

		meetings to discuss findings and identify patterns (if any) These meetings will be conducted via GoToMeeting.com or a similar technology to provide for shared display of documents.		Epidemiologist MA Coalition MA Senior Care MAssPro HAI Coordinator
		Interview analysis written	11/12	Evaluation Team Epidemiologist
		SNA maps produced	11/12	Evaluation Team
		Presentation of findings prepared based on interview analysis and SNA maps	12/12	Evaluation Team Epidemiologist
		Final deliverable binder compiled and delivered	12/12	Evaluation Team Epidemiologist

Appendix A: Outcome Measures for the Existing CDI Implementation Project

Table of Process and Outcome Measures			
Measure	Definition	Numerator	Denominator
PROCESS MEASURES			
Key collaborative features	Evidence of the four key attributes of a strong prevention collaborative; (Multidisciplinary advisory group, dedicated staffing, effective communication strategy and a system to measure outcomes).	Number of features for which there is documented evidence	Four
Collaborative Participation	# long-term care facilities and acute care hospitals participating in collaborative.	Number of facilities by type	NA
Statewide Participation	#long-term care facilities and staff participating in statewide offerings	Number of facilities Number of staff	NA
Leadership commitment	Percent of participating facilities that have provided signed letters of leadership commitment	Number of facilities with signed letters	Number of participating facilities
Infection prevention practice performance	Results of Baseline Prevention Practice Assessment Tool. To be completed at baseline and again at end of program.	Number of LTC facilities with given characteristics	Number of LTC facilities
Degree of engagement	Percentage of LTC facilities participating in collaborative events and meeting collaborative expectations	Number of LTC facilities participating in activities (attend meetings, testing, etc.)	Number of LTC facilities
OUTCOME MEASURES			
Change in CDI Rate in LTC partner facilities	Comparison of health care acquired CDI rates in LTC facilities during baseline and program periods - Hospital Acquired, Other Health Care Facility, and Community Acquired	CDI cases per the NHSN lab ID definition	10,000 resident/patient days
Change in Acute Care Hospital CDI Rates	Comparison of CDI rates in Collaborative Hospitals during baseline and program periods: disaggregated by Hospital Acquired, Other Health Care Facility, and Community Acquired.	CDI cases per the NHSN lab ID definition	10,000 patient days
Avoided hospital admissions from LTC	Change over time in admissions to all hospitals with diagnosis of CDI or sequellae of CDI (codes to be determined)	LTCF documentation of admissions to all hospitals with any CDI dx or other specific codes	LTC Resident days during time periods
LTC-Acquired CDI Burden within Collaborative partners	Change over time in patients admitted to participating hospitals from partner LTCFs with diagnosis of CDI or sequellae of CDI (codes to be determined)	Admissions to participating hospitals from partner LTCFs with any CDI dx or other specific codes	LTC Resident days during time periods

Appendix B: Tools: Social Network Analysis Draft Data Collection Questions and Interview Guide

Social Network Analysis Data Collection Questions

1. "With whom do you work on CDI efforts?"
2. "Over the past 12 months, from whom have you gotten new ideas or inspiration that helped you in your CDI reduction efforts?"
3. "List projects and activities and people you have worked with on those projects."
4. "Who would you like to work with during the coming year on MRSA reduction efforts?"

Phone and Site Visit Interview Guide

The sample guide below was exhaustively developed and tested during an earlier MRSA reduction project. It is anticipated that this guide will be slightly modified for use in evaluating the CDI efforts.

Implementation Stories Interview Guide

1. What were the two or three most important activities or tasks that were implemented as part of the MRSA project?
2. What worked well to engage providers and staff? What did you do to overcome barriers such as lack of time and attention? Please give an example.
3. What data are being collected, analyzed and used by front-line staff? What do front-line staff tell you about what data are meaningful for them? Please give an example.
4. What staff did you encounter resistance from (physicians, nurses, etc.)? How did you know you were facing resistance? How was the resistance dealt with or overcome? What resistance did you encounter from physicians? How was that dealt with?
5. How did you determine whether the implementation was successful or not? How do you know that you got some return on your investment?
6. What worked well? (Be sure to get the "How" using probes such as: How were you able to accomplish this? How did you get this to work?). Please give an example of this.
7. What didn't work well? Why? Please give an example of this.
8. What are your three key learnings?
9. If there is time:

What surprised you about this project?

Share a critical incident or incidents that you think tells the story about the project.

What activities are planned to sustain the change?

Source: Developed by cross-organizational research team for an MRSA collaborative, Spring, 2010. Members included: Brad Doebbeling, Shawn Hoke, Mindy Flanagan, Amber Welsh, Regenstreif Institute, Sharon Benjamin, Plexus Institute, Patricia Arling, Assistant Professor of MIS at Butler University, Alicia Bergman, *Indiana Health Services Research Fellow*.

ATTACHMENT 5

WEST NILE VIRUS AND OTHER ARBOVIRAL DISEASES

a) *Background, Need and Understanding*

Massachusetts has two arboviral diseases of public health concern caused by West Nile virus (WNV) and eastern equine encephalitis (EEE). The state's population of approximately 6.5 million in an environment that contains highly urban areas most conducive to the *Culex* species mosquitoes that transmit WNV and the white cedar and red cedar swamps that are the preferred habitat of the EEE enzootic vector, *Culiseta melanura*.

West Nile virus infection: Since 2001 when the first case was identified, between three and 22 cases occur annually. Cases are identified most frequently in Suffolk, Middlesex and Worcester county residents who represent 46% of the total population. The majority of confirmed cases occur in residents over the age of 50, an age group that is generally considered to be at highest risk for severe disease; there are 1.3 million people in that demographic.

Eastern equine encephalitis (EEE): EEE was first identified as a human pathogen in Massachusetts in 1938 and there have been regular epidemic cycles of disease since that time. Only Florida has more confirmed human cases of EEE. The southeastern counties of Bristol and Plymouth have historically borne the brunt of EEE activity based on the presence of appropriate habitat; their combined population of just over one million is at annual risk of disease. A smaller focal area of EEE habitat and activity has developed more recently in extreme northeastern Massachusetts along the border with New Hampshire.

Surveillance for WNV and EEE activity relies almost entirely on mosquito trapping and testing. Mosquito trapping is done by both the Massachusetts Department of Public Health (MDPH) and multiple local mosquito control projects (MCPs). Viral testing is done exclusively at the MDPH Hinton State Laboratory Institute (HSLI). Trapping and testing burdens vary by year, directly in response to virus activity. However, budgetary constraints in both federal and state funding sources have led to decreases in field and laboratory staff, as well as laboratory supplies, resulting in an overall decrease in surveillance capacity. In 2006, 9,334 pooled mosquito samples were tested and in 2010, the total number was 3,558.

The MDPH work on arboviruses is conducted by staff in several different divisions. The Arbovirus Program sits within the Bureau of Laboratory Sciences (BLS) and coordinates MDPH mosquito trapping, testing and data collection, analysis of data, collaboration with the MCPs, the State Reclamation and Mosquito Control Board (SRMCB), and the Mosquito Advisory Group (MAG), and assesses risk for human cases. The Virology and Molecular Diagnostics Laboratories within the BLS conduct testing of all mosquito, animal and human specimens. The Epidemiology Program within the Bureau of Infectious Disease (BID) is responsible for communication and outreach to physicians, local boards of health (LBOH), the public and the media. All three areas work very closely to rapidly and accurately assess risk and communicate prevention strategies to Massachusetts residents.

Despite budgetary constraints, MDPH continues to work closely with the MCPs responsible for mosquito trapping and nuisance control to be collectively vigilant for the emergence of new mosquito species vectors capable of supporting new or existing arboviral diseases of public health concern, such as dengue or chikungunya. In 2010, isolated *Aedes albopictus* specimens were first trapped in Massachusetts, and in 2011 this species was submitted to DPH for testing.

Surveillance for clinical animal and human cases with symptoms consistent with either WNV or EEE infection also occurs through the Epidemiology Program and all specimen testing is done at HSLI. Positive WNV and EEE results from commercial laboratories are followed-up with interview and confirmatory testing at HSLI. Presumptive viremic donors identified by blood collection are also interviewed.

Between 2005-2010, Massachusetts has been in the top ten states reporting travel-associated dengue cases to the CDC, primarily through testing by commercial diagnostic laboratories. Because dengue became a reportable disease in 2009, MDPH will propose to add dengue screening to its current passive arboviral surveillance to capture more of these travel-associated cases.

All surveillance information is compiled and used to define areas of risk for human infection with a mosquito-borne illness. This risk information is tied to specific response activities at both the local and state levels, involving public health and mosquito control. All surveillance and response activities are detailed in an annually reviewed, multiagency Arbovirus Surveillance and Response Plan that is posted on the MDPH website.

Maintenance of operation of the arbovirus surveillance program will ensure that MDPH can continue to provide timely, accurate risk assessments that serve as the basis of both mosquito disease control efforts and real-time public health messaging to Massachusetts residents.

b) Operational Plan

Activity 1: Maintenance of human surveillance activities for WNV and other arboviral diseases of public health importance. Basic requirements of a human surveillance program should involve:

- 1) Participation in ArboNET, the computerized national surveillance system developed to track activity of WNV and other arboviral diseases of public health importance. CDC requests weekly submission of data during the transmission season, including:
 - a) Human cases meeting current case definition
 - b) Presumptive viremic blood donors

Arbovirus Program staff will upload the following to ArboNET weekly:

- Human WNV and EEEV positive results and appropriate demographic data.
- Results for evidence of infection by other arboviruses found in human specimens.
- Information on presumptive viremic blood donors as it becomes available from the blood centers

- 2) Maintenance and/or enhancement of laboratory capacity to identify WNV and other arboviral infections in humans. Testing protocols include but are not limited to assays to detect immunoglobulin (Ig) M, IgG, and neutralizing antibodies (e.g., enzyme-linked immunosorbent assay [ELISA], microsphere immunoassay [MIA], and plaque reduction neutralization tests [PRNT]), nucleic acid amplification tests (e.g., real-time detection [RT-PCR]), virus isolation techniques and virus identification using virus-specific monoclonal antibodies (requires BSL3 level containment).

Laboratory staff will:

- Screen for WNV and EEEV human infections using IgM and IgG EIAs.
- Screen for dengue human infections using an IgM capture ELISA and using RTD-PCR (real-time detection PCR).
- Use PRNT to confirm EIA reactive specimens via assay for WNV, EEEV, and SLE specific antibody (sera and/or CSF from non-human species may be tested by PRNT).
- Test CSF specimens and serum from meningoencephalitis and encephalitis cases by cell culture; excess CSF may be tested by RTD-PCR for rapid WNV/EEEV diagnosis.
- Test samples from clinically suspicious horses and select other species (e.g., emu, llama, alpaca) (pre-screened for rabies virus) by RTD-PCR and/or cell culture.

The State Public Health Veterinarian and Epidemiology Program staff:

- Facilitate sample collection for WNV/EEEV from clinically suspicious horse cases and from select other species (e.g., emu, llama, alpaca) with neurologic symptoms.
 - Obtain and confirm clinical specimens testing positive for WNV at commercial laboratories during local WNV transmission season.
 - Maintain communication with MA Department of Agricultural Resources (MDAR) and USDA regarding surveillance for and testing of suspect animal WNV and EEE cases.
- 3) Participation in the WNV laboratory proficiency program to evaluate laboratory capacity to perform WNV MIA/ELISA, PRNT and PCR assays.

Laboratory staff, under the direction of the Virology and Molecular Diagnostics Laboratory Director, will:

- Maintain CLIA compliant laboratory practices by participating in the CDC Arboviral Branch's annual proficiency testing program in which one PT survey for each RTD-PCR, IgM and IgG EIAs, and PRNT assay are completed. Supplemental in house PT surveys will be completed for these same assays as needed.
- 4) Data analysis and interpretation and dissemination of results.

Arbovirus Program staff will:

- Perform statistical analyses of potential predictors of risk for human disease, such as mosquito infection rates.
- Produce weekly summary reports of surveillance data for LBOHs and MCP officials.
- Report human WNV and EEE cases by phone to MCPs within four hours of confirmed results.

Epidemiology Program staff will:

- Report human WNV and EEE cases by phone to appropriate health care providers (HCP) and LBOHs within four hours of confirmed results.
- Post WNV and EEEV information regarding human and animal cases, mosquito results and updates to risk assessment maps to the MDPH arbovirus public website within 24 hours.
- Provide sample press releases describing assessment of human risk based on current surveillance findings to LBOHs upon their request.

Year 1 (1/1/12 –12/31/12):

- By 01/01/12, the Virology and Molecular Diagnostics laboratories will continue to test human clinical specimens submitted for arbovirus testing.
- By 05/31/12, the State Public Health Veterinarian will work with the State Veterinarian at the MDAR to perform outreach to large animal veterinarians regarding surveillance and testing of animal clinical cases.
- By 06/30/12, the Epidemiology Program staff will have updated notification protocols for reporting of human and animal cases, posting all surveillance information to the web daily and updated draft press releases for use by LBOHs.
- By 07/01/12, sample collection and testing on animal clinical specimens will begin and continue for the duration of the local transmission season.
- By 07/01/12, Virus Serology staff will verify and implement dengue IgM capture ELISA for screening human cases.
- By 07/01/12 Molecular Diagnostics staff will validate and implement dengue RTD-PCR for supplementing diagnostic testing of human cases.
- By 07/15/12, the Arbovirus Program staff will begin analyzing data from the 2012 season and will produce weekly reports for distribution.
- By 12/31/12 the Virology and Molecular Diagnostics laboratories will have participated in the CDC's annual proficiency testing.

Years 2-5 (1/1/13-12/31/16)

Throughout years 2-5 all activities above will continue. As needed, laboratory diagnostic assays for new or emerging arboviral diseases of public health concern in Massachusetts will be implemented.

Activity 2: Maintenance or expansion of environmental surveillance systems to include:

- 1) Participation in ArboNET, the computerized national surveillance system developed to track activity of WNV and other arboviruses of public health importance. CDC requests weekly submission of data during the transmission season, including:
 - a) Positive environmental surveillance results (e.g., mosquitoes, dead birds, sentinel animals, veterinary cases, etc.)
 - b) Denominator data describing the total number specimens tested as part of environmental surveillance programs.

Arbovirus Program staff will upload the following to ArboNet weekly:

- All mosquito numerator and denominator data.
 - Equine, llama, alpaca or other animal WNV and EEEV positive results and appropriate demographic data.
- 2) Maintenance and/or enhancement of laboratory capacity to identify WNV and other arboviruses of public health importance for environmental surveillance purposes. Specific environmental surveillance activities include sustaining capabilities to capture, identify and test mosquito vectors, avians, and other vertebrates for infection with WNV and other arboviruses of public health importance.

Arbovirus Field staff will:

- Set mosquito traps in areas with historic arbovirus activity, increased activity late in the previous season, and locations that could serve as virus amplification sites as determined by ecological survey. Sites will be fixed or flexible depending upon ecological surveys and surveillance and distributed in collaboration with the nine different MCPs.
- Perform routine trapping for *Culiseta melamurai* using CDC light traps at the long-term fixed sites and in areas with EEEV activity detected in 2004 through 2010. CO₂ baited traps will be added at these sites to collect putative bridge vectors.
- Set BG Sentinel mosquito traps, if funding permits, in selected areas to provide surveillance for the presence of *Aedes albopictus*.
- Hire seasonal staff, if funding permits, and train on mosquito collection, identification, and pool processing.
- Ensure statewide procedures for gravid and light trap deployment will continue, with added trap sites for collection of potential bridge vectors. Collections will begin by 7/15/2012.

Laboratory staff will:

- Ensure mosquito pools are tested for WNV and EEE virus following a rapid screening and identification algorithm using real time detection PCR (RTD-PCR).
- Investigate reports of unusual avian mortality and procure specimens for viral studies (EEEV) if appropriate.

The State Public Health Veterinarian will:

- Investigate reports of unusual avian mortality and procure specimens for viral studies (EEEV) if appropriate.

- 3) Conduct data analysis and interpret and disseminate results.

Arbovirus Program staff will:

- Enter mosquito abundance and mosquito pool test results into the WNV database for tracking and analysis.
- Ensure access to mosquito results by epidemiologists and MCPs in real time via the MDPH web-based database.
- Send notifications for positive mosquito arboviral findings to directly affected MCPs via phone and email.
- Perform statistical analyses of potential predictors of risk, such as mosquito infection rates.
- Create reports of surveillance data to distribute to LBOHs and (MCP) officials.

Epidemiology Program staff will:

- Send notifications for positive mosquito arboviral findings to directly affected LBOHs and LBOHs of bordering towns via the Massachusetts Alert Network (HHAN).
- Post WNV and EEEV information regarding mosquito pool results and updates to surveillance maps to the MDPH WNV public website within 24 hours.

Year 1 (1/1/12 –12/31/12):

- By 06/01/12, Virus Isolation staff performs viral cell culture on all *Aedes albopictus* pools submitted for RTD-PCR testing of WNV and EEE virus.
- By 06/30/12, the Arbovirus Program Staff hires seasonal staff and begin training.
- By 06/30/12, Epidemiology Program staff updates notification protocols for reporting of mosquito sample positive results, posts all surveillance information to the web daily and updates draft press releases for use by LBOHs.
- By 07/15/12, the Arbovirus Program Staff starts mosquito trapping for the season and mosquito testing in the laboratories.
- By 07/15/12, the Arbovirus Program staff begins analyzing data from the 2012 season and produces weekly reports for distribution.
- By 07/15/12, the State Public Health Veterinarian begins investigating avian mortality reports for possible arboviral testing.

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5 all activities above will continue.

Activity 3: Support prevention and educational activities for WNV and other medically important arboviruses.

- 1) Provide timely updates on arbovirus transmission activity for use by local jurisdictions in implementing vector management and public education activities.

Arbovirus Program staff will:

- Schedule and coordinate WNV/EEEV planning meetings to review surveillance findings, solicit input on statewide WNV activities and review the existing Massachusetts Arbovirus Surveillance and Response Plan. Changes will be made to the plan, based on participant feedback and in conjunction with the CDC's Revised Guidelines for WNV Surveillance, Prevention and Control.
- Attend the annual Northeast Mosquito Control Association meeting to present a programmatic overview and promote public health messages.

Epidemiology Program staff will:

- Maintain a recorded information line with information about arboviral diseases, their transmission and ways to reduce the risk of exposure.
- Provide emergency on-call coverage 24/7.
- Develop educational lectures and displays and provide them throughout the season upon request, to both professionals and the public, in a variety of forums.

- Coordinate and participate in regional public health conference calls to discuss regional arboviral findings and strategies.
- Respond to questions about risk assessment from LBOHs.
- Support the information line 24/7, May through October.
- Produce an annual summary of arbovirus activity.

2) Provide access to public education materials to local jurisdictions.

Epidemiology Program staff will:

- Provide updated WNV and EEEV fact sheets, prevention resource guides and an updated Arbovirus Surveillance and Response Plan to all LBOHs and MCPs in the spring.
- Distribute relevant updated information through the HHAN, the web and a mailing to physicians, hospitals, blood donations centers, etc.

Year 1 (1/1/12 –12/31/12):

- By 01/01/12, 24/7 on-call coverage will continue.
- By 03/30/12, all educational materials and lectures will be updated with 2011 end-of-season data.
- By 05/15/12, the first meeting with the MCPs, Arbovirus Program staff, Laboratory Staff and Epidemiology Program staff will be held to plan for the arbovirus season.
- By 05/30/12, relevant educational materials will have been distributed via the HHAN to all stakeholders.
- By 06/30/12, the Massachusetts Arbovirus Surveillance and Response Plan will have been completely reviewed, updated, approved and posted to the public website.
- By 06/01/12, the recorded information line will be changed from influenza messaging to arbovirus messaging.
- By 11/30/12, Arbovirus Program Staff will have attended the Northeast Mosquito Control Association meeting.
- By 12/31/12, the arbovirus annual summary will be completed and posted on the public website.

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5 all activities above will continue

c) Measures of Effectiveness/Measurable Goals

- 1) Maintain or enhance diagnostic laboratory capacity and proficiency to conduct human surveillance for WNV and other arboviral diseases of public health importance.
 - a) Number of arbovirus assays the state diagnostic laboratory is capable to perform and demonstrated proficiency in key assays for which proficiency evaluation is provided (data reported in Tables 3 and 4).

Effectiveness will be indicated by maintaining the capacity to perform WNV, EEE and SLE assays at HSLI. Improvement will be indicated if the capacity to run dengue virus

assays is added. Proficiency effectiveness will be indicated by participation in the EIA, PRNT and PCR proficiency panel evaluation.

- 2) Report all identified human cases of WNV and other arboviral diseases of public health importance to ArboNET.

- a) Number of cases of arboviral diseases, including WNV, reported via ArboNET.

Effectiveness will be indicated if all laboratory confirmed cases are reported to ArboNET. Confirmation that all cases are reported will be achieved by comparing weekly summary reports to ArboNET data.

- 3) Report all WNV presumptive viremic donors to ArboNET.

- a) Number of WNV presumptive viremic donors reported to ArboNET

Effectiveness will be indicated if all WNV presumptive viremic donors known to MDPH are reported to ArboNET. Confirmation that all cases are reported will be achieved by comparing epidemiologist of the day (EOD) notes to ArboNET data.

- 4) Increase the proportion of public health laboratory confirmed human disease cases from WNV and other arboviral diseases of public health significance reported to ArboNET.

- a) Ratio of confirmed cases to probable-suspect cases reported to ArboNET.

All confirmatory testing for arboviral diseases endemic to Massachusetts is performed at HSLI which enables MDPH to ensure that all confirmed cases are available for reporting to ArboNET. This measure of effectiveness will not be used since 100% of laboratory confirmed cases are already reported.

- 5) Report all numerator and denominator data for dead birds and mosquitoes tested for WNV and other arboviral diseases of public health importance.

- a) Proportion of local jurisdictions (e.g., counties) conducting mosquito or dead bird surveillance with data reported to ArboNET (from Table 6).

Effectiveness will be indicated if all numerator and denominator data for mosquitoes tested for WNV and EEE are reported to ArboNET. Confirmation that all cases are reported will be achieved by comparing weekly summary reports to ArboNET data. However, each of the 351 municipalities in Massachusetts makes an individual decisions to participate or not in regional Mosquito Control Projects. Therefore, MDPH does not have control over the proportion of local jurisdictions conducting mosquito surveillance. This measure of effectiveness will not be used. It is unlikely that the proportion of jurisdictions participating will change substantially from what is currently reported in Table 6.

Table 1. WNV ELC expenditures by category: January 1, 2011 through June 30, 2011. In March 2012, the CDC will request verified data for January 1, 2011 – December 31, 2011.

Spending category	Amount (\$)
Personnel – Epidemiology*	\$30,723
Personnel – Laboratory*	
Supplies*	\$3,348.00
Equipment*	
Travel*	
Indirect Costs*	\$4,547.00
Grants and contracts	
Other expenditures (please specify below) Fringe	\$10,728.00
Unspent: We anticipate all funds will be spent	
Total FY11 WNV award plus any carryover or unspent used	\$49,346.00
*Include actual expenditures from the ELC program at the state or district health department level.	

Table 2. WNV ELC expenditures by activity: 1/1/2011 through 6/30/2011. In March 2012, the CDC will request verified data for 1/1/2011 – 12/31/2011.

Program activity	Amount (\$)
Human surveillance*	\$45,998.00
Environmental surveillance†	\$3348.00
Education/community outreach	
Vector control	
Other expenditures (please specify below)	
Unspent	
Total FY11 WNV award plus carryover or unspent used	
*Includes all ELC-supported human surveillance activities (e.g., diagnostics, epidemiology and reporting of human disease cases, viremic blood donors) †Includes all ELC-supported environmental surveillance activities (e.g., mosquito collection/testing, dead bird collection/testing, veterinary cases, sentinel animals etc.)	

Table 3. Applicant diagnostic laboratory arbovirus testing capacity: 1/1/2011 through 6/30/2011*. *In 3/2012, the CDC will request data for 1/1/2011 – 12/31/2011.*

	ELISA		MIA		IFA		PRNT	PCR
Virus	IgM	IgG	IgM	IgG	IgM	IgG		
California serogroup†								
Chikungunya								
Colorado tick fever								
Dengue								
Eastern equine encephalitis	X	X					X	X
Japanese encephalitis								
Powassan								
St. Louis encephalitis							X	
Western equine encephalitis								
West Nile	X	X					X	X

Table 4. WNV diagnostic proficiency panel evaluation: 1/1/2011 through 6/30/2011. *In March 2012, the CDC will request data for 1/1/2011 – 12/31/2011.*

Panel	Participated in 2011	
Enzyme-linked immunosorbent assay/Microsphere immunoassay	X Yes	<input type="checkbox"/> No
Plaque reduction neutralization test	X Yes	<input type="checkbox"/> No
Polymerase chain reaction	X Yes	<input type="checkbox"/> No

Table 5. Number of human specimens tested by your laboratory for WNV anti-IgM antibodies: 1/1/11 through 6/30/11. *In 3/2012, the CDC will request data for 1/1/11 – 12/31/11.*

Specimen type	Number of human specimens tested for WNV anti-IgM antibodies
Serum	75
Cerebrospinal fluid	42
Total	117

Table 6. Arboviral surveillance and control programs by county: 1/1/11 through 6/30/11*.
In 3/2012, the CDC will request data for 1/1/11 – 12/31/11

County name (list)†	Any arboviral surveillance performed				Mosquito control program
	Mosquito pools	Dead birds	Sentinel chickens	Live/wild birds	
1. Barnstable	30				Cape Cod
2. Berkshire	15				Berkshire
3. Bristol	58				Bristol
4. Dukes	2				Cape Cod
5. Essex	67				North East
6. Middlesex	81				Central Massachusetts, East Middlesex
7. Norfolk	26				Norfolk
8. Plymouth	46				Plymouth
9. Suffolk	64				Suffolk
10. Worcester	86				Central Massachusetts

ATTACHMENT 6

LYME DISEASE

a) Background, Need and Understanding

Massachusetts continues to be one of 10 states where Lyme disease is endemic. The 2010 incidence rate was 40 cases per 100,000 persons. However, the summer of 2010 was unusually hot and dry in Massachusetts and reports of all tick-borne diseases were decreased for the year, likely due to reduced tick survival. In 2009, the incidence rate was 63 cases per 100,000, a rate that is more consistent with previous year's findings. Peak incidence rates occur in children under 18 and in adults ages 50-69. Massachusetts has approximately three million people in these age groups combined.

In general, Massachusetts has a well-developed infectious disease surveillance system and has also made significant progress in electronic laboratory reporting (ELR). The Massachusetts Department of Public Health (MDPH) currently receives electronic laboratory reports from 61 out of 74 hospital laboratories in the state as well as from two large commercial laboratories. Regulations require that all laboratory reports be transmitted electronically so work is on-going to enroll the remaining hospitals and commercial laboratories.

MDPH receives 8,000-14,000 positive Lyme disease test results from laboratories annually. Every positive result generates a request to the ordering healthcare provider (HCP) for clinical information on the patient. A second request for information is generated. The completeness of information collected on Lyme disease cases is entirely dependent upon the HCP completing the case report form (CRF) as individual follow-up is not possible given current resource limitations.

The activities proposed in this section are entirely dependent upon the ability to retain a part-time epidemiologist, whose duties are focused on maintaining current Lyme disease surveillance activity. This individual is responsible for data evaluation and analysis utilizing case report information captured through the already existing electronic surveillance infrastructure. Case data is fully analyzed annually in order to produce a surveillance report. However, this individual will also begin running quarterly reports to identify missing data from recently received reports. This will enable some individual follow-up with providers to improve data completeness.

In an effort to better understand the limitations of physician-based case reporting, MDPH will cooperate with a large healthcare organization (HMO) that is currently developing automated electronic medical record (EMR) reporting capabilities. A reliable algorithm for extracting information on a list of all patients diagnosed with Lyme disease meeting the criteria for a confirmed or probable case (by HMO providers) has been developed. By sending a teleform to the HCP for each of these cases, the percentage of those returned can be evaluated and used to estimate the percentage of cases that go unreported.

MDPH is also considering, depending on additional funding, a one-year pilot project to assess the impact of ELR on Lyme disease case reporting. Sentinel sites that began submitting laboratory reports electronically in 2010 or 2011 will be enrolled. Medical records will be

reviewed for one year prior to electronic reporting being initiated and one year after to capture all diagnosed cases of Lyme disease with Lyme laboratory testing. These will be compared with information received by the Office of Integrated Surveillance and Informatics Services (ISIS) to: 1) evaluate the completeness of reporting of positive laboratory data and 2) assess the proportion of positive labs noting results for which clinical information is received. The assumption has been that ELR actually improves case reporting. However, a 2008 Lyme disease survey of HCPs found that 50% assume that they do not need to report cases because they know that the laboratory will. It is conceivable that ELR may decrease the number of completed CRFs received on patients.

b) Operational Plan

Activity A: Core Surveillance: Perform surveillance for Lyme disease. Conduct data analysis, interpret, and disseminate results.

MDPH staff will:

- Maintain a part-time epidemiologist for Lyme disease surveillance and data analysis activities.
- Receive and maintain a database of reports within ISIS, consisting of Lyme disease cases and positive laboratory results as required by Massachusetts' regulations.
- Ensure the Lyme disease epidemiologist runs quarterly reports to identify case reports with missing county of residence information with subsequent request to HCP for information.
- Report confirmed and probable cases of Lyme disease and appropriate demographic data to CDC via NEDSS from ISIS.
- Analyze surveillance data to identify key demographic or geographic parameters and produce an annual surveillance summary report, including that year's incidence map by town, as directed by the State Public Health Veterinarian (SPHV).
- Distribute annual surveillance summary to all local boards of health (LBOH), to HCPs through the Massachusetts Medical Society (MMS) and post on the MDPH website as directed by the SPHV.
- Respond to requests for information and statistics on Lyme disease from the media, members of the public, HCPs and local public health officials through the SPHV and ISIS.
- Participate in any scheduled Lyme disease conference calls and in-person meetings hosted by CDC through the SPHV, and/or their specific designee(s).

Year 1 (1/1/12 –12/31/12):

- By 1/1/12, the part-time epidemiologist will be retained by MDPH.
- By 1/1/12 a letter requesting missing case data will be available for mailing to HCPs.
- By 4/15/12 all CRFs received to date will be classified as confirmed, probable, suspect or not a case. Data will then be available for public release in response to requests for information.
- By 5/1/12 all Lyme disease case reports received to date will be analyzed and reported in the annual surveillance summary and will include an incidence map.
- By 6/1/12 the report will be posted to the website, distributed to all 351 LBOH and submitted to MMS for inclusion in their newsletter.

- By 12/31/12, we will have participated in all scheduled quarterly conference calls and in-person meetings.

Years 2-5 (1/1/13-12/31/16)

Throughout years 2-5 all activities above will continue.

Activity B: Innovation: Develop, refine, or enhance existing surveillance capacity and activities to create a more sustainable and informative Lyme disease surveillance system.

MDPH will:

- Evaluate completeness of case report data to identify demographic fields with greatest proportion of missing data and summarize completeness of data and geographic distribution analyses in an informal report to disseminate to HCPs and LBOHs as directed by the SPHV.
- Work with large HMO through ISIS to receive EMR reports of Lyme disease cases and assess proportion of CRFs that are received out of all medical record-based reports.

Year 1 (1/1/12 –12/31/12):

- By 5/1/12 all Lyme disease case reports received to date will be analyzed for data completeness and an informal summary report will be produced.
- By 6/1/12 the report will be distributed to all 351 LBOHs and submitted to MMS for inclusion in their newsletter.
- By 12/31/12 will have met with ISIS to arrange receipt of EMR reports.
- By 06/30/12 a part-time contractor will be hired to conduct medical record review and sentinel sites will be enrolled (dependent upon receipt of additional funding).
- By 12/31/12 medical record review will be complete and data analysis to evaluate the effect of ELR on Lyme disease case reporting will begin.

Years 2-5(1/1/13-12/31/16):

By 3/1/13 receipt of EMR reports will begin. Throughout years 2-5 all activities above will continue dependent upon assessed effectiveness

c) Measures of Effectiveness/Measurable Goals

The following measurable goals will be reported on for each reporting period over the five years of the grant cycle as required. Please see each goal for current status, current availability of requested information or examples of how the information will be provided using 2011 information.

Activity A & B

- 1) Number of qualified personnel hired or retained

One part-time epidemiologist is retained to perform Lyme disease surveillance activities.

- 2) Number of personnel trainings conducted (Activity A & B)

Part-time epidemiologist is to be retained and no additional training is required. This measure will not be used.

Activity A:

- 3) Number of confirmed and probable Lyme disease cases reported to CDC (via NEDSS) in a timely manner

Information on when a case report is completed, when it is reviewed and when it is reported to CDC is captured and stored in an electronic database developed and maintained within ISIS (MAVEN). Of the 3,227 confirmed and probable Lyme disease cases from 2010 reported to CDC, 98% of them were transmitted within 90 days of the case report review date. 100% of them were reported within 160 days or just over five months.

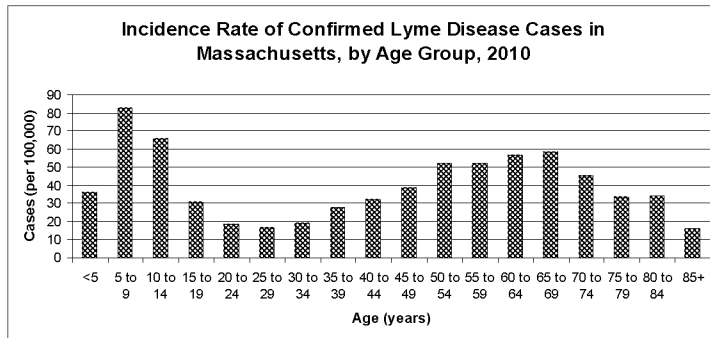
- 4) Number of cases classified as suspect and/or not-a-case

The MDPH case classification for Lyme disease deviates from the national one in the suspect category. MDPH captures all positive laboratory reports without accompanying clinical information in this category. Number of suspect cases will not be used as a measure of effectiveness. However, MDPH does review all cases for whom clinical information is received and revokes those that do not meet the case definition. In 2010, there were 768 reviewed cases classified as not a case.

- 5) Evaluation of key demographic or geographic parameters (used to target prevention)

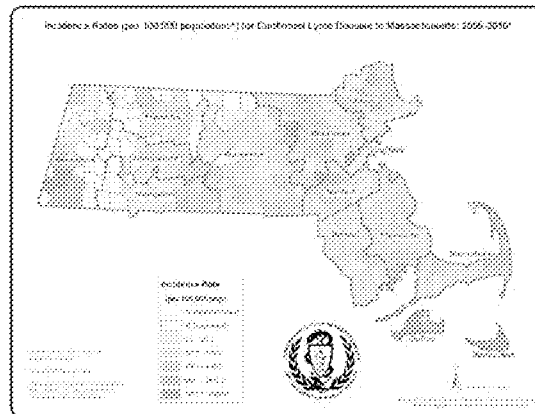
Data is analyzed for this annually and the information is included in the annual surveillance summary. Inclusion in the annual summary indicates successful completion of goal. The age-adjusted and county of residence incidence rates are presented from 2010 data.

County*	2010 Confirmed Cases (#)	2010 Incidence Rate (per 100,000)
Barnstable	117	54
Berkshire	93	71
Bristol	141	26
Dukes	25	151
Essex	184	25
Franklin	42	59
Hampden	130	28
Hampshire	80	51
Middlesex	414	28
Nantucket	27	265
Norfolk	267	40
Plymouth	230	47
Suffolk	34	5
Worcester	252	32
State Total	2593	40



- 6) Development of maps detailing endemic counties and/or high-risk areas (annually evaluated).

A map is produced by ISIS geographic information system specialist using data after it has been cleaned and analyzed. Data is provided to GIS staff and map is produced for inclusion in annual surveillance summary. Inclusion in the annual summary indicates successful completion of goal. The incidence map for 2010 is included below.



- 7) Number and type of improvements in data due to routine data quality/completeness checks.

Annual comparisons between the data quality analysis reports will be done. Improvement will be indicated by a decreasing percentage of missing data in identified fields of interest (see #10).

- 8) Number of quarterly Lyme calls with state participation.

At least one individual will be assigned to each scheduled quarterly call. The assigned individual will participate on the call and provide a brief written summary to all program epidemiologists regarding the call.

- 9) Number of reports (webpage, annual reports) disseminated having summary data

The Lyme disease annual surveillance summary is distributed via an electronic alerting network to all 351 LBOH once it is completed. It is not currently possible to track the number of website

visits to a specific page, however, the state government website is currently undergoing a complete renovation. The potential for tracking visits utilizing the new site will be assessed.

Activity B

- 3) Development and dissemination (e.g. to public health partners of informal reports regarding quality and coverage of surveillance data)

Information regarding cases within an unknown town and county of residence is already included in the annual Lyme disease surveillance summary. A more complete analysis of missing data to include race/ethnicity, date of symptom onset, and tick exposure will be performed and disseminated via the electronic alerting network to all 351 LBOH.

- 4) Percentage of licensed HCPs, diagnostic laboratories, and/or hospitals in jurisdiction providing Lyme disease case reports to the state

As not all HCPs are likely to practice in specialties relevant to Lyme disease diagnosis and treatment, MDPH does not intend to use the percentage of licensed HCPs submitting case reports to the state as a measure of effectiveness. Currently, 82% of hospital labs in Massachusetts transmit Lyme disease laboratory test results electronically. Only two large commercial laboratories in Massachusetts report electronically (as opposed to paper reports). However, the commercial laboratory responsible for the majority of tick-borne disease testing in the state is currently working towards electronic reporting. Improvement will be demonstrated if there is an increase in the number of total laboratories reporting electronically.

- 5) Number of CRFs submitted by providers

The fact that a case report is received from a provider is documented in the surveillance database and can readily be extracted. In 2010, there were 8,995 individuals with some type of Lyme disease report information submitted, either clinical data or laboratory results or both. CRFs were received on 6,405 of them. Improvement will be demonstrated by an increase in the proportion of total reports with an associated CRF.

- 6) Percent of case reports that are complete at the time of submission

The MDPH CRF collects symptom information in a yes/no/unknown format. Providers frequently do not answer for symptoms not displayed by their patient. This does not truly represent an incomplete CRF. Analysis for data completeness will be done using designated fields of particular importance including town and county of residence, symptom onset date, race/ethnicity and tick exposure. Improvement will be demonstrated by year-over-year decreases in the percentage of incompletely captured data.

ATTACHMENT 8

INFLUENZA

a) Background, Need and Understanding

Influenza surveillance in Massachusetts consists of both epidemiologic and laboratory components to monitor disease in approximately 6.5 million residents. The Immunization Program, within the Bureau of Infectious Disease (BID), is responsible for influenza surveillance as well as its control and prevention. The Massachusetts Department of Public Health (MDPH) Hinton State Laboratory Institute's (HSLI) Virus Isolation and Molecular Diagnostics Laboratories, part of the Bureau of Laboratory Sciences (BLS), are responsible for influenza diagnostic efforts. During the 2010-2011 season, 658 cases of PCR and culture-confirmed influenza were reported to the MDPH as well as over 10,000 cases of influenza confirmed by rapid influenza diagnostic test. Laboratory-confirmed influenza cases represent only a small percentage of the total burden of influenza in the state, as many individuals do not seek treatment for influenza and many of those who seek treatment are not tested for the illness. MDPH uses data from the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) outpatient surveillance system to monitor timing and intensity of influenza activity throughout each season. Peak levels of influenza-like illness since the 2007-2008 influenza season have ranged from 2.65% in the 2010-2011 season to a peak of 9.25% in the 2009-2010 season, during the second wave of 2009 H1N1 activity.

Influenza testing at the HSLI includes respiratory virus culture for isolation and subtyping as well as PCR, which was added in 2009. HSLI laboratory staff will begin implementing ELC-ACA funded pyrosequencing methods for influenza resistance surveillance during the 2011-2012 season. Separately, HSLI has been selected, as one of a few public health laboratories, to assist the CDC Influenza Branch with evaluation of TaqMan low-density array using the ViiA 7 platform for detection of a number of respiratory pathogens. This type of approach is also central to our desire of combining molecular approaches along with virus isolation for the purpose of broadening respiratory illness surveillance. The bureau components responsible for influenza surveillance (Immunization Program and the Virus Isolation and Molecular Diagnostics Laboratories) are located in the same building, thus facilitating frequent meetings and collaboration on influenza surveillance efforts in the state. To enhance HSLI virologic surveillance, lab staff and the influenza surveillance coordinator will coordinate and collaborate with hospital-based laboratories to receive virologic testing data to bolster virologic surveillance across the state.

HSLI provides influenza testing services for diagnostic and virologic surveillance purposes. Specimens are submitted through the sentinel system, described below, as well as for diagnostic purposes from non-sentinel sites in unusual/severe cases or when the results may have public health impact. Nasopharyngeal collection kits, which include swabs, viral transport media and mailing tubes, are provided by the HSLI and all testing is provided free-of-charge. Prior to the 2009 H1N1 pandemic, the HSLI tested approximately 250-500 specimens annually, with about 50% of specimens submitted from sentinel/ILINet sites. Specimen volume rose significantly

during the pandemic and submission guidelines were changed to focus on surveillance and diagnostic testing in cases of clinical or public health significance. During the 2010-11 season, the HSLI tested nearly 500 specimens, approximately half of which were submitted by ILINet sites. The laboratory performs differential diagnostic testing for other respiratory pathogens (e.g., adenovirus, RSV, and parainfluenza types 1-3.) primarily using virus isolation techniques. Resources are needed to support differential diagnostic testing throughout the year using molecular and virus isolation techniques.

MDPH currently uses an electronic laboratory reporting (ELR) system that was deployed in October 2004 for infectious diseases reporting to the Massachusetts Virtual Epidemiologic Network (MAVEN), which is a web-based surveillance system using HL7 messaging utilized by MDPH. ELR provides laboratories and other health care partners with the ability to check and receive reports electronically. The system also serves as a single point of entry for Massachusetts hospitals, clinics and other health care providers to electronically order tests from HSLI, receive test results, and finally view the status of test orders.

Currently 63 hospitals and commercial laboratories use ELR to electronically report their laboratory results to MDPH's MAVEN, including 61 of 73 acute care hospitals in the state, as well as HSLI. We expect all Massachusetts hospitals to participate in ELR by early 2013. MAVEN allows the epidemiologist to capture additional demographic and clinical information. MDPH currently captures limited case-based information, but is exploring methods with which to collect racial/ethnic and clinical data, with a focus on exploring inequities and identifying high-risk cases in a timely manner. MAVEN is also used to track and document clusters of influenza-like illness (ILI) and to link those clusters to positive laboratory reports. For those sites that will not have an ELR software license due to small volumes, funds for instrumentation to scan specimen submission forms are needed so that both the laboratory and epidemiology department can view this information electronically. This is particularly important for small facilities and sentinel sites that may not be able to utilize ELR mechanisms.

Using the same ELR web portal, hospital and other clinical laboratories are able to send data electronically on all reportable conditions to BID. To do this, clinical laboratories utilize the ELR web interface to create mappings between BID selected LOINC and SNOMED codes and the local laboratory equivalents. HSLI currently sends all influenza test results to MAVEN in HL7 2.3.1 format. In addition, HSLI has been reporting all influenza testing results since 2010 to CDC in real time using HL-7 PHLIP format via PHIN-MS.

Since 1998, MDPH has participated in the U.S. Influenza Sentinel Surveillance Project, now called the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet). Currently, there are 57 sites across the state enrolled in this project (approximately 2.2 sites per 250,000 population) and recruitment is ongoing. This exceeds the ratio of 1 per 250,000 as recommended by CDC. Included in the 57 ILINet sites are 13 office locations of a large multispecialty provider network serving over 10 percent of the state's population. These sites, part of Atrius Health, use an automated protocol to detect cases of ILI using ICD-9 codes in conjunction with the presence of fever, and report these cases along with their total visits per week by generating automated reports that are sent to MDPH and forwarded to CDC. These data were validated

with the influenza surveillance group at CDC and have substantially expanded the coverage of the ILINet system in Massachusetts. Sentinel sites report ILI weekly throughout the influenza season and are encouraged to report during the summer interseason as well.

In addition to ILI reporting, ILINet sites submit nasopharyngeal swabs from select patients for testing. Sites are asked to submit up to two specimens per week throughout the traditional influenza season (October through March) as part of surveillance efforts, as well as for any cases of ILI during the summer months or in cases with unusual presentation or travel history. To minimize delays in result reporting, additional providers need to be set up to use ELR

Starting in the fall of 2009 as part of enhanced surveillance for H1N1, acute care hospitals throughout the state were asked to voluntarily submit weekly data on the number of hospitalizations and deaths in persons with laboratory-confirmed influenza. Thirteen hospitals participated in the pilot year for this project during the 2009-2010 season and 55 of 72 acute care hospitals in Massachusetts participated in this surveillance program during the 2010-2011 season. Reporting is done using an internet-based survey tool and MDPH is currently exploring ways to better integrate these data into MAVEN.

Epidemiology staff also collect data from the investigation of reported clusters of ILI at long-term care facilities and other institutions. Unusual cases and clusters reported to MDPH are investigated as well. Suspected cases of novel influenza A virus infection are reportable to MDPH, as are any pediatric influenza-related deaths. Following recognition of an increased burden of disease and mortality rate from 2009 H1N1 in pregnant women, MDPH also began requesting that physicians report any ICU admissions and deaths in pregnant women immediately. Lastly, nine cities in Massachusetts report deaths from influenza and pneumonia on a weekly basis to CDC. State-wide electronic mortality surveillance is not yet available in Massachusetts, awaiting the introduction of electronic death reporting (EDR) through the Registry of Vital Records and Statistics. Current plans estimate that EDR will be available by 1/1/2013.

The most significant gaps in influenza surveillance capacity at MDPH include the continued need for comprehensive electronic mortality surveillance, improved demographic and geographic representation within the ILINet program, and more timely and complete ILI reporting and specimen submission by ILINet providers. The ELC-funded epidemiologist position will aid in the implementation of EDR for influenza; until EDR is available, the epidemiologist must optimize current systems of influenza death reporting, including pediatric influenza death reporting and the reporting of laboratory-confirmed deaths by acute care hospitals. The expansion and diversification of the ILINet provider network and communication with existing providers to improve on current rates of reporting and specimen submission require a substantial time commitment by the influenza epidemiologist. In addition to existing unmet needs, the epidemiologist is essential to facilitate any enhancements or improvements necessary to existing surveillance systems as recommended by CDC and CSTE. From the laboratory testing and reporting perspective, gaps exist in improving the laboratory reporting speed and efficiency by ELR which can be solved by setting up larger providers with a ELR software license.

Over the five year award period, the ELC-funded influenza epidemiologist and Immunization Program staff will continue building, validating and improving Massachusetts' well-established influenza surveillance and testing program. By the end of the first 12-month period, MDPH plans to expand and diversify the network of ILINet sites, add hospitals to our laboratory-confirmed influenza hospitalizations surveillance system and explore ways to better utilize electronic sources of morbidity data. Over the five year award period, MDPH also plans to implement measures to expand on current influenza surveillance data using electronic sources of morbidity data, better integrate current data streams into MAVEN and begin use of an EDR to track influenza morbidity data. Throughout the five year award period, MDPH will continue to improve the timeliness and completeness of ILI reporting, including reporting throughout the summer interseason and increasing the number of specimens submitted by ILINet sites to the HSLI laboratory for virologic surveillance. The influenza epidemiologist will conduct ongoing reviews of influenza data for quality and completeness and will implement improvement measures as needed. The influenza epidemiologist will continue to act as the primary point of contact for CDC at MDPH and will report significant cases according to existing protocols and will collaborate with CDC in efforts to improve national and state-level influenza surveillance.

A. Influenza Surveillance

b) Operational Plan

Activity 1: Expand and enhance ILINet participation, including virologic specimen submission. Arrange for year-round reporting from a subset of sites.

Massachusetts currently has 57 ILINet sites throughout the state. While this number is well above the recommended one site per 250,000 population, there is room for improvement in the timeliness and regularity of reporting and geographical representation. All currently enrolled sites have reported for some portion of the weeks in the 2010-2011 influenza season; however, some sites reported for only a limited number of weeks while others reported for most weeks but submitted data much later than the weekly reporting deadline, making data less useful. In addition, while some regions of the state contain a large number of reporters, particularly concentrated around the large cities of Boston and Worcester, areas of the western and southeastern regions of the state remain poorly represented. A primary responsibility of the influenza epidemiologist is to optimize reporting from existing sites and increase the coverage and diversity of the ILINet system in Massachusetts. In the past two years, MDPH has also focused more on influenza testing for surveillance; MDPH now requests up to two specimens per week from all ILINet sites as compared to six specimens per season requested prior to 2009 H1N1. These specimens are tested for influenza as well as an expanded respiratory panel that includes adenovirus, RSV and parainfluenza. Throughout the award period, the epidemiologist will continue efforts to expand and diversify the ILINet system and to encourage regular specimen submission to increase the efficacy of virologic surveillance in the state.

Year 1 (1/1/12-12/31/12):

- Between February and April 2012 MDPH will host an informational conference call for ILINet sites, including updates on influenza activity and current recommendations.

- By May of 2012, the epidemiologist will contact ILINet sites about interseasonal ILI reporting and enlist $\geq 25\%$ of enrolled sites to report ILI throughout the summer.
- By September of 2012, the epidemiologist will recruit ILI sites as needed to ensure that each of Massachusetts' seven surveillance regions includes at least four regularly reporting sites.
- By October of 2012, staff will send specimen collection kits to sites at the beginning of the season via regular mail, to be returned via an overnight mail delivery service or courier for free influenza and respiratory virus panel testing. Additional kits will be sent to ILINet sites throughout the season as needed.
- Throughout the year, staff will target recruitment efforts to increase the geographic coverage and diversity of the sites in order to ensure representative population-based information, with a focus on sites (hospitals, emergency departments) that will identify influenza in specific subpopulations (e.g., high-risk groups, children, healthy adults, those likely to travel or have visitors particularly from Asia and the Southern Hemisphere).
- During influenza season (from 1/1/12 through 5/19/12 and from 9/30/12 through 12/31/12), the epidemiologist will contact sites regularly to ensure they are both reporting ILI and submitting specimens for testing appropriately.
- Throughout influenza season, support is offered to all sites as needed, especially those not meeting reporting and specimen submission goals. This may include telephone support, educational materials and/or possible site visit.
- During influenza season, data are summarized in weekly activity reports sent to ILINet physicians and laboratories and posted on MDPH's influenza website, and in an annual report and other reports as needed.
- During influenza season, the epidemiologist will respond to ILI outbreaks, including sending specimen collection kits to outbreak facilities and arranging transportation of samples to HSLI via courier or an overnight mail delivery service to facilitate diagnosis and outbreak control.

Years 2-5 (1/1/13-12/31/16):

On a yearly basis, the epidemiologist will continue to recruit sites to increase geographic coverage and increase diversity of patient populations covered by surveillance sites; they will continue efforts towards increasing the number of specimens submitted to HSLI from ILINet sites and increase the number of ILINet sites that submit specimens on a regular basis ($\geq 50\%$ of weeks in flu season). On a yearly basis, staff will continue efforts towards increasing the proportion of ILINet sites reporting regularly (≥ 16 weeks throughout the season) with an emphasis for all sites on timely reporting. Each year in the late winter/early spring, MDPH will host a conference call for ILINet sites. Each May a proportion of enrolled ILINet sites will be recruited to report throughout the interseason. At the end of each season, the influenza epidemiologist will analyze all laboratory-confirmed influenza reported to MDPH, including rapid influenza reports. This will be compared to previous seasons. On an ongoing basis, the epidemiologist will recruit additional ILINet sites that are currently using electronic data sources to report their weekly data to CDC and to compare it with traditionally gathered ILI data.

Activity 2: Report significant cases to CDC according to existing protocols and explore additional electronic methods of influenza morbidity and mortality surveillance. Facilitate the improvement of influenza surveillance as recommended by the Council of State and Territorial Epidemiologists (CSTE).

Since the fall of 2006, MDPH has collected and managed infectious disease surveillance data using the MAVEN online surveillance system. For influenza, the primary role of MAVEN has been to store information on positive laboratory findings indicative of influenza as well as document reported clusters of influenza-like illness. While the system has the capacity to store additional clinical and demographic information and was used for case investigation during 2009 H1N1, there is currently no automated method with which to collect comprehensive demographic and clinical data on a routine basis. During the 2011-2012 season, MDPH will send an automated teleform for ordering providers to complete and return for each positive influenza PCR or culture result reported through MAVEN. These teleforms are currently able to collect only basic information, but possible methods to collect expanded data on these cases are under investigation. In addition to providing additional demographic information describing the burden of influenza disease in Massachusetts, these data will aid the epidemiologist in identifying high risk cases in a timely manner and offering the potential to provide guidance on testing and treatment on a situational basis. Additional clinical data will also help the epidemiologist better track severity of disease during the course of the influenza season.

First implemented in the late summer of 2009 in response to the circulation of 2009 H1N1, MDPH collects aggregate counts of laboratory-confirmed influenza hospitalizations and deaths on a weekly basis using an internet-based survey tool. Fifty-five of 72 acute care hospitals in the state reported data during the 2010-2011 season, with an average of 49 hospitals reporting each week. These data are currently collected using an internet-based survey tool and MDPH is exploring methods to integrate these data into MAVEN. An additional electronic source of influenza morbidity data currently available to MDPH includes rates of influenza-like illness in Massachusetts emergency departments through the AEGIS syndromic surveillance system. The system is maintained by research partners at the Children's Hospital Informatics Program. This system will be maintained through the 2011-2012 system, but funding for the program beyond that time period is uncertain.

Development of an electronic death reporting system continues by the Massachusetts Registry of Vital Records and Statistics. Once funding has been secured and the system is rolled out, MDPH will work with the Massachusetts Registry of Vital Records and Statistics to utilize this capability to monitor influenza-related deaths in a timely way and integrate the death data into MAVEN. Pediatric influenza deaths are reportable in Massachusetts, and clinicians are reminded through advisories and other clinical guidance annually to report any suspected or confirmed deaths due to influenza in pediatric patients immediately to MDPH.

Year 1 (1/1/12-12/31/12):

- By July of 2012 staff will explore possible methods of integrating laboratory-confirmed influenza hospitalization and death reporting into MAVEN surveillance system.

- By September of 2012, the epidemiologist will recruit an additional 5 Massachusetts acute care hospitals to participate in the laboratory-confirmed influenza hospitalizations and deaths reporting program.
- By September of 2012 staff will work with the Bureau of Vital Statistics as they continue development of an electronic death reporting system. Staff will develop a detailed plan for implementation and integration of the electronic death reporting system into MAVEN, with a primary focus being influenza mortality surveillance.
- During influenza season (from 1/1/2012 through 5/19/2012 and from 9/30/2012 through 12/31/2012), the epidemiologist will weekly activity level for the State and Territorial Epidemiologists Report.
- During influenza season the epidemiologist will use MAVEN to collect limited clinical and demographic data on PCR and culture-confirmed influenza cases and will explore methods to utilize MAVEN to collect expanded demographic and clinical information in future seasons.
- During influenza season, the epidemiologist will monitor reports of laboratory-confirmed influenza hospitalizations and deaths, pediatric influenza deaths and other unusual deaths related to influenza infection and follow up as needed.
- During influenza season, the influenza epidemiologist will monitor and respond to rates of influenza-like illness in Massachusetts emergency departments, as detected by the AEGIS syndromic surveillance system.
- Throughout the year, the epidemiologist will report all influenza-related pediatric deaths through CDC's Secure Data Network.
- Throughout the year, the epidemiologist will fully investigate all cases and suspect cases of novel influenza A using MDPH's detailed protocol which includes the collection of epidemiologic information, and also assist with specimen collection and guidance with control measures.

Years 2-5 (1/1/13-12/31/16):

The epidemiologist will continue working with the Office of Integrated Surveillance and Informatics Services (ISIS) to improve and expand influenza data collected through the MAVEN system. This expansion will include both the implementation of new or improved methods of data collection as well as outreach to clinicians to reinforce the importance of timely and complete reporting. Together with the Massachusetts Registry of Vital Records and Statistics, the immunization program will continue collaboration to integrate the electronic death reporting data into MAVEN; following implementation, all deaths listing influenza as a cause of death will be reviewed by Immunization Program epidemiologists. On a yearly basis, the epidemiologist will review recommendations from CDC and CSTE regarding improvement of influenza surveillance and implement enhancements to existing systems as needed.

c. Measures of Effectiveness/Measurable Goals:

Activity 1:

- The number of ILINet sites remains above 52 (two sites per 250,000 population), with at least one regularly reporting site per 250,000 population, and additional sites are recruited to

increase geographical and demographic diversity. *Baseline:* 57 sites during 2010-2011 season.

- At least 70% of ILINet sites report regularly (≥ 16 weeks of the influenza season). *Baseline:* 69% in 2010-2011 season.
- Reporting by ILINet sites is monitored weekly and follow up occurs on a monthly basis with non-reporting sites.
- At least 60% of ILINet sites submit at least two specimens during the influenza season. *Baseline:* 53% in 2010-2011 season.
- At least 20% of ILINet sites submit specimens for at least eight weeks of the influenza season. *Baseline:* 14% in 2010-2011 season.
- Emails with up-to-date flu information, recommendations and surveillance data are sent to all ILINet sites throughout the year.
- An annual conference call between MDPH and the ILINet sites is held at least once per season. Additional calls may be added to address major changes in procedures, recommendations or influenza activity.
- A minimum of 25% of surveillance sites continue to report regularly (≥ 10 weeks) and submit specimens as appropriate during the interseason. *Baseline:* 25 sites seeing patients in the summer reported during the 2011 interseason (44%).
- Analysis of all laboratory-confirmed influenza reported to MDPH, including rapid influenza reports, is conducted at the end of the influenza season and compared to previous seasons.
- Historical baselines are established incorporating several years of ILINet and laboratory data, using methodology established and made available by CDC. Baseline data is integrated into weekly data analysis throughout the season.

Activity 2:

- The State and Territorial Epidemiologists Report is submitted to CDC each week during the influenza season. *Baseline:* 100% during 2010-2011 season.
- All influenza-related pediatric deaths are reported through the National Notifiable Diseases Surveillance System within 24 hours of notification, with case report forms completed within one month of death. *Baseline:* one (total) case (100%) was reported within 24 hours and completed within one month during 2010-2011 season.
- All reported cases or suspect cases of novel influenza A are fully investigated and appropriately tested. *Baseline:* One case of suspected H5N1 infection was investigated and ruled out in June 2010.
- The MAVEN surveillance system is maintained to summarize and track ILI information, outbreak data, clinical data and demographics on pertinent cases. Data are reviewed throughout the season to monitor data quality.
- Complete aggregate influenza hospitalization and death data is collected from acute care hospitals throughout Massachusetts using an internet-based system. *Baseline:* 55 of 72 acute care hospitals participated in reporting in 2010-2011 season, with an average of 49 hospitals reporting per week.
- MDPH continues development of its electronic death reporting system to identify deaths from influenza and pneumonia in a timely manner, with availability anticipated by 1/1/13.

B. Influenza Diagnostic Testing

b) Operational Plan

Activity 1. Expand laboratory capacity to perform influenza virus detection (by PCR and culture), typing and sub-typing year round.

The Massachusetts Hinton State Laboratory Institute's (HSLI) Virus Isolation and Molecular Diagnostics laboratories, within the Bureau of Laboratory Sciences (BLS), will continue to work closely to maintain expanded laboratory testing capacity year-round.

Laboratory staff will:

- Perform year-round virus isolation, as well as typing and sub-typing of influenza viruses using both molecular and antigen-based methods.
- Maintain year-round the ability to detect avian and novel influenza viruses using PCR-based assays (H5a and H5b targets).
- Perform real-time reporting of influenza test results by HSLI to the CDC (U.S. WHO) using HL-7 PHLP format via the Public Health Information Network Messaging System (PHIN-MS).
- Ensure (semi-monthly) systematic submission of influenza virus isolates and clinical material, based on CDC Influenza Branch guidelines, to the CDC for the purposes of providing representation from Massachusetts for national virologic surveillance.
- In coordination with the Influenza Surveillance Coordinator, the lab staff will continue efforts to collaborate and coordinate with hospital-based laboratories and rapid influenza testing sites across the state to submit virologic testing results data and specimens for further virologic testing.
- The lab staff will coordinate with the LIMS administrator to ensure annual mapping of new PHLP messages for each influenza season.
- The LIMS administrator will coordinate with the Molecular Diagnostics Division Director to ensure that new providers will be set up and trained with an ELR license in order for their facility to receive electronic laboratory test results.

Year 1 (1/1/12-12/31/12):

- From 1/1/2012, continue to send five of the most recent and representative influenza isolation and/or matching clinical material every two weeks to the designated CDC contract lab.
- Year-round, notify CDC immediately of all influenza A unsubtypeable or inconclusive indicating possible swine origin influenza for further characterization; prepare for immediate shipping.
- Year-round, maintain all PCR-based assays to detect avian and novel influenza viruses and notify CDC immediately of all suspect avian influenza; prepare for immediate shipping.
- During influenza season (from 1/1/2012 through 5/19/12 and from 9/30/12 through 12/31/12), lab staff will coordinate with the Influenza Surveillance coordinator to supplement influenza surveillance samples by soliciting additional influenza original specimens and virus isolates (usually type Bs) for further characterization.

- During influenza season (from 1/1/12 through 5/19/12 and from 9/30/12 through 12/31/12), lab staff will coordinate with the Influenza Surveillance coordinator to acquire virologic test result data from other clinical diagnostic laboratories to supplement HSLI virologic surveillance data.
- By November 2012 (start of each influenza season) or as new strains emerge, the lab staff and LIMS administrator will map new PHLP messages.
- By 12/30/12, 100% of the ELR licenses will be put into use by facilities submitting samples for influenza testing.

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5 all activities above will continue.

c) Measures of Effectiveness/Measurable Goals:

- Year-round HSLI submits 100% of its influenza test results to CDC within two weeks of the test date.
- HSLI submits a minimum of 20 influenza virus isolates to CDC for further characterization each influenza season.
- HSLI continues to demonstrate proficiency in PCR methods for influenza virus detection, typing, and subtyping by enrolling in a proficiency testing program and scoring 80% or better as per CLIA qualifications.
- Year-round, 100% of influenza A viruses tested by HSLI are subtyped.
- HSLI identifies at least three sites to submit their virologic test result data to supplement the HSLI virologic data for the 2011-2012 season.
- Year-round, new or emerging influenza strains are mapped to new PHLP messages within 14 days.
- HSLI puts into use 100% of the ELR licenses by 12/31/12.

ATTACHMENT 12

OTHER INFECTIOUS DISEASES NOT ELSEWHERE COVERED

A. Rabies

a) Background, Need and Understanding

The raccoon rabies virus variant was first detected in Massachusetts in 1992 and is currently enzootic in the state. Between 1992 and December 2010, 49,408 terrestrial mammals and 10,242 bats have been submitted for rabies testing to the Massachusetts Department of Public Health's (MDPH) Hinton State Laboratory Institute (HSLI). In 2010, 117 terrestrial mammals (7% of terrestrial mammal submissions) and 14 bats (2% of bat submissions) tested positive for rabies using the direct fluorescent antibody test (DFA) protocol that is considered to be the gold standard.

Based on testing results in 2010, rabies exposure was ruled out in 89% of cases that resulted in animal submissions. However, 130 specimens were not tested due to incomplete specimen submission or tissue decomposition. This represents half of the 11% of cases in which rabies exposure could not be ruled out. While the combination of an unsatisfactory DFA test and a negative PCR test could not conclusively be reported out as a negative specimen, a positive PCR test from an unsatisfactory DFA specimen would provide definitive information for risk assessment purposes. The PCR equipment utilized for the real time detection PCR assays are maintained by service contracts on the PHEP grant. HSLI molecular technical staff funded by both the PHEP and base ELC will assist the Rabies laboratory with bringing this assay online.

An essential component of rabies surveillance is the identification of non-endemic virus strains that may occur through animal importation or sustained transmission of bat rabies strains in terrestrial mammal populations, such as has occurred in Arizona. Detecting these events requires timely antigenic characterization of the infecting virus strain in positive animals. In 2010, strain typing was performed on only 50 of the 131 positive animals.

The United States Department of Agriculture (USDA) is conducting an oral rabies vaccine distribution program in Massachusetts due to the unique geographic barrier provided by the Cape Cod Canal that separates the Cape Cod peninsula from the mainland. USDA is also conducting enhanced surveillance for rabies by using the direct rapid immunohistochemical field test (DRIT) on suspect animals not involved in human or domestic animal exposures. This testing data augments rabies surveillance in Massachusetts.

The Rabies Laboratory sits within the Bureau of Laboratory Sciences' (BLS) Division of Virology and Molecular Diagnostics. All rabies specimen testing on animals with reported human or domestic animal contact is done exclusively through this facility. The laboratory maintains a database which collects all specimen submission information and testing results. The Epidemiology Program sits within the Bureau of Infectious Disease and is responsible for all human risk assessment consultation, educational outreach, and post-exposure prophylaxis treatment recommendations following laboratory testing.

Adding molecular diagnostics to our current rabies specimen testing protocol will enhance our ability to detect rabies in specimens that are not able to be tested using DFA. While DFA remains the gold standard and results will be reported out based on that test only, PCR testing will provide additional information to support both risk assessment and surveillance. Assuming that unsatisfactory specimens would have the same positivity rate as satisfactory ones, five additional rabid animals would be detected within the first 12 months. These results from our laboratory would enable the epidemiologists responsible for risk assessment to provide a more accurate assessment for exposed humans and domestic animals. Over a five year period, an additional 25 rabid animals detected would improve our surveillance by a minimum of 3.5%.

Increasing the proportion of positive specimens that are tested for antigenic characterization of the virus and performing that testing on at least a quarterly basis, will improve our capacity to detect, and the timeliness at which we are able to detect, new rabies strains or the occurrence of current rabies strains in new species. During the first year, the expectation is that at least 50% of rabid animals would have strain typing performed with increases in the percentage tested in subsequent years. Strain typing will be performed quarterly during the first year with the option to increase testing to monthly over the five year period, dependent upon funding.

MDPH and the Rabies Laboratory are interested in participating in the future on development or validation of any new assays for either diagnostic or strain characterization purposes. Potentially, this work could be used to help standardize laboratory protocols for use within a broader testing network across multiple states.

b) Operational Plan

Activity 1: Provide training on detection of rabies using the national standard protocol for Direct Fluorescent Antibody (DFA) testing.

Laboratory staff will:

- Have received training on the national standard DFA protocol.
- Continue to participate in the Wisconsin State Laboratory of Hygiene's Rabies Proficiency Testing Program for DFA with PT samples being shipped twice per year.

Activity 2: Enhance or implement immunological and/or molecular diagnostics to accurately detect rabies and improve viral characterization

Laboratory staff will:

- Perform PCR testing on specimens that test unsatisfactory by DFA and have reported human or domestic animal contact as the reason for submission.
- Perform strain characterization on all specimens testing positive by DFA on a quarterly basis.

Year 1 (1/1/12 –12/31/12):

- By 6/30/12, the Rabies Laboratory staff will verify and implement a raccoon-specific rabies RT-PCR assay.

- By 6/30/12, the Rabies Laboratory staff will verify and implement a universal rabies RT-PCR assay.
- By 6/30/12, molecular rabies testing results will be added to the rabies database for inclusion in the rabies surveillance reports.
- By 12/31/12, all specimens unsatisfactory by DFA will be tested by PCR within 24 hours.
- By 12/31/12, 50% of rabies positive specimens from 2012 will have strain characterization performed on them within three months of submission.
- By 12/31/12, Rabies Laboratory staff will include available sources of bat-specific strain typing reagents to allow identification of bat strains.

Years 2-5 (1/1/13-12/31/16):

Throughout years 2-5, all activities above will continue with the expectation that by the end of year five, 100% of rabies positive specimens will have strain characterization performed within at least three months of submission. The Rabies Laboratory staff will continue to participate in the WSHL Rabies Proficiency Testing Program and maintain an 80% or above testing score.

Activity 3: Improve routine surveillance and epidemiology of rabies

Program staff will:

- Include specimens tested by the USDA using DRIT and confirmed by the CDC rabies lab in our annual rabies surveillance report and map.
- Include specimens tested by HSLI using PCR in our annual rabies surveillance report and map.
- Include strain typing information in the annual rabies surveillance report and map.

Year 1 (1/1/12 –12/31/12):

- By 3/30/12, DRIT rabies positive specimens from 2011 will be added to the 2011 annual rabies surveillance summary that is publicly posted on our website and distributed to local rabies control partners.
- By 12/31/12, PCR testing data will be included in the 2012 annual rabies surveillance summary.
- By 12/31/12, strain typing information will be included in the next quarter report and in the 2012 annual rabies surveillance summary.

Years 2-5(1/1/13-12/31/16):

Throughout years 2-5 all activities above will continue

c) Measures of Effectiveness/Measurable Goals

- 1) Number of human exposures reported

We will not be using this as a measure of effectiveness as none of the activities proposed will change the number of human exposures reported.

- 2) Number of human vaccination episodes avoided

The number of people with exposures to a rabies suspect is provided on the specimen submission form and is entered into the HSLI Rabies Laboratory database. Both DFA and PCR results will also be entered and the number of individuals exposed to all specimens unsatisfactory by DFA testing can be easily extracted. Of these, individuals exposed to low risk species that ultimately test negative by PCR can be counseled that post-exposure prophylaxis is unnecessary and will be tallied as human vaccination episodes avoided. This information will also be captured in the rabies consult database that documents all risk assessments done by epidemiologists.

3) Number of isolates collected from suspect animals that are characterized.

All specimens submitted for rabies testing and the corresponding information on the specimen submission form are entered in the HSLI Rabies Laboratory database. A data field exists for collection of strain typing information. This information is readily extracted and analyzed and will be done during the quarterly rabies data analysis. Data will be presented as a proportion of all positive specimens in order to measure progress against the stated goal of at least 50% during each quarter.

4) Number of suspected rabies cases investigated

We will not be using this as a measure of effectiveness as none of the activities proposed will change the number of suspected rabies cases investigated. All submitted specimens that test positive or unsatisfactory are followed-up to identify both human and domestic animal contacts for risk assessment.

ATTACHMENT 12

OTHER INFECTIOUS DISEASES NOT ELSEWHERE COVERED

C. Tickborne Disease Surveillance and Response (not including Lyme disease)

a) Background, Need and Understanding

Endemic transmission of five of the ten commonly recognized tick-associated human illnesses occurs in Massachusetts: Lyme disease, babesiosis, human granulocytic anaplasmosis (HGA), tularemia, and rarely, Rocky Mountain spotted fever.

Babesia infection has been reportable in Massachusetts for two decades. Transmission occurs most frequently on the Cape and Islands, Plymouth and Bristol counties in southeastern Massachusetts and in the metropolitan area immediately west of Boston. Up to 100 cases have been confirmed annually and the number has been increasing rapidly over the last five years. About half of the cases that occur are hospitalized. Between five and 10% of cases are investigated for possible transfusion transmission of disease.

Approximately 60 cases of HGA are reported annually in Massachusetts. As with other tick-borne disease, the Cape and Islands report some of the highest incidence rates although an area of intense transmission occurs in the southwest corner of the Commonwealth. One-quarter of reported cases result in hospitalization. Cases occur in all age groups although those between the ages of 45 and 69 are disproportionately affected.

In 2000, an outbreak of pneumonic tularemia occurred on Martha's Vineyard (MV) associated with occupational exposure; brush-cutting and lawn-mowing. While the number of pneumonic cases that occurs each year varies, MV remains an active focus for tularemia transmission. Between three and 16 confirmed and probable cases occur annually and have occurred in pneumonic, septic, typhoidal and glandular forms. Cases in domestic animals, primarily cats, are also identified annually and continue to represent an additional source of exposure for veterinarians and pet owners.

Cases of locally acquired RMSF in Massachusetts residents are rare but they do occur. Due to the emphasis that is placed on deer-tick associated diseases, RMSF may be under-recognized by healthcare providers.

The Massachusetts Department of Public Health's (MDPH) Hinton State Laboratory Institute (HSLI) does not perform any testing for tick-borne diseases, except tularemia. Virtually all public health activity on tick-borne disease is conducted by the Epidemiology Program within the Division of Epidemiology and Immunization. Epidemiologists rely on the data obtained through electronic laboratory reporting (ELR) to the Office of Integrated Surveillance and Informatics Systems (ISIS) to identify suspect cases. Suspect case information is provided to local boards of health (LBOH) for investigation. Once clinical information is provided, review by an epidemiologist occurs. Some laboratory reports are received without appropriate

demographic information which prevents assignment of suspect cases to LBOHs for case investigation.

Laboratory test results on tick-borne disease can be complicated and many LBOHs are unfamiliar with the tests and their interpretation. Epidemiologists frequently spend time consulting with LBOHs on their suspect cases and providing advice on follow-up prioritization. In addition, prompt review of completed case report forms (CRFs) is essential for babesiosis cases in order to rapidly identify the possibility for transfusion transmission. When a suspect transfusion-associated transmission is identified, contact with the blood center is necessary in order to remove potentially infected blood from the supply and to initiate a donor recall.

Case investigation by many LBOHs is hampered by lack of understanding of laboratory data and a lack of priority placed on tick-borne disease case follow-up. In 2010, epidemiologists conducted enhanced surveillance for cases of babesiosis and HGA by following-up on all PCR test results for which there was no corresponding clinical information obtained. This enhanced surveillance resulted in increases of 33% in the confirmed case counts of both diseases. As the number of suspect cases being reported to MDPH continues to increase, the proportion of cases with incomplete clinical information increases and the degree to which each disease is under-reported actually increases. Some level of enhanced follow-up will continue to be necessary by MDPH to support the activities of the LBOHs.

Annual summary surveillance reports are produced and distributed to LBOHs and other public health stakeholders.

b) Operational Plan

Activity 3: Build and/or expand epidemiological capacity to measure burden, trends, and to track emergence of (non-Lyme) tickborne diseases, including: babesiosis, human granulocytic anaplasmosis (HGA), human monocytic ehrlichiosis (HME), Rocky Mountain spotted fever (RMSF), Southern tick-associated rash illness (STARI), tick-borne relapsing fever (TBRF), and tularemia. [Please see Section 5 on “West Nile virus and other arboviral diseases”, for guidance involving Colorado tick fever and Powassan encephalitis].

Program staff will:

- Contact healthcare providers of suspect cases with positive PCR results for either babesia or HGA to obtain clinical information if the LBOH has not obtained that information within two weeks of receipt of the initial report.
- Contact healthcare providers of suspect cases with positive babesia smear results to obtain clinical information if the LBOH has not obtained that information within two weeks of receipt of the initial report.
- Contact laboratories for complete demographic information on reports missing town of residence information.
- Provide informal quarterly reports on the number of incomplete CRFs on all non-Lyme tickborne diseases to LBOHs.

- Produce annual surveillance summaries for all tick-borne diseases and distribute to LBOHs and post publicly for healthcare providers and the public.
- Annual reports on data quality will be completed for babesia and HGA and disseminated to LBOHs.

Year 1(1/1/12 –12/31/12):

- By 3/31/12, a part-time non-Lyme tick-borne disease epidemiologist will be hired.
- By 06/1/12, the part-time epidemiologist will be trained and will be following-up on positive laboratory reports and contacting laboratories for demographic information.
- By 06/01/12, quarterly reports on data quality will be produced and disseminated to LBOHs via the electronic alerting network.

Years 2-5(1/1/13-12/31/16):

By 3/31/13, 2012 annual surveillance summaries will be produced and posted on the public website and distributed to LBOHs. The final data quality report will also be completed. All other activities will continue

c) Measures of Effectiveness/Measurable Goals

- 1) Hiring or retention of qualified personnel.
 - a) Percentage of staff positions for the activity that are filled
One half-time epidemiologist is retained to perform non-Lyme tick-borne disease surveillance activities.
- 2) Training of personnel.
 - a) Number of trainings attended
The epidemiologist will be trained by existing staff and will not require outside training. This measure will not be used.
- 3) Reporting of confirmed and probable cases to CDC in a timely manner.
 - a) Number of confirmed cases reported to CDC within specified days of detection
Information on when a CRF is completed, when it is reviewed and when it is reported to CDC is captured and stored in an electronic database developed and maintained within ISIS. Improvement will be demonstrated by a decrease in the number of days between case report form review and transmission to CDC.
- 4) Development and dissemination (e.g. to public health partners) of informal reports regarding quality and coverage of surveillance data.
 - a) Percentage of quarterly reports distributed to partners
Information regarding cases within an unknown town and county of residence is already included in the annual surveillance summary. A more complete analysis of missing data to include, reports with incomplete follow-up, race/ethnicity, date of symptom onset, and tick exposure will be performed annually and disseminated via the electronic alerting

network to all 351 LBOHs. Quarterly reports on the number of laboratory reports with incomplete follow-up will occur quarterly if an epidemiologist position is funded.

- 5) Steps taken towards development or expansion of information technologies or electronic reporting.

ISIS will continue to pursue 100% ELR. However, this is an activity separate from the activities proposed for the tick-borne disease epidemiologist. This measure will not be used.

- 6) Development of pilot projects designed to better understand the incidence of tickborne diseases or their pathogens in a defined area.

- a) Number of counties that monitor tickborne pathogens

Enhanced follow-up on laboratory reports likely to be associated with a confirmed case, PCR babesia and HGA results, for example, will improve understanding of the true incidence of tick-borne diseases other than Lyme disease in Massachusetts. Improvement will be demonstrated by a decrease in the proportion of cases with incomplete clinical information. There are currently no MDPH supported programs that monitor tick-borne disease pathogens in any county in Massachusetts. This measure will not be used.

- 7) Assignment of suspect cases to town of residence

Contacting laboratories for demographic information on suspect cases associated with positive laboratory reports will allow assignment of suspect cases to a town of residence which enables forwarding of the information to the LBOH for case investigation. Improvement will be demonstrated by a decrease in the proportion of cases that cannot be assigned to a town and county of residence.

ATTACHMENT 12

OTHER INFECTIOUS DISEASES NOT OTHERWISE COVERED

D. Capacity Building for Waterborne Disease Detection, Investigation, and Reporting.

a) Background, Need and Understanding

Massachusetts is the fourteenth most populous state in the nation, with over six million people distributed over 351 cities/towns. Only five of these cities/towns have populations greater than 100,000, while approximately 270 have populations less than 20,000 (US Census).

Data for Massachusetts show that the five most populous cities or towns and their 2010 Census counts are Boston, 617,594; Worcester, 181,045; Springfield, 153,060; Lowell, 106,519; and Cambridge, 105,162. Boston grew by 4.8 percent since the 2000 Census. Worcester grew by 4.9 percent, Springfield grew by 0.6 percent, Lowell grew by 1.3 percent, and Cambridge grew by 3.8 percent.

The largest county is Middlesex, with a population of 1,503,085. Its population grew by 2.6 percent since 2000. The other counties in the top five include Worcester, with a population of 798,552 (increase of 6.3 percent); Essex, 743,159 (increase of 2.7 percent); Suffolk, 722,023 (increase of 4.7 percent); and Norfolk, 670,850 (increase of 3.2 percent).

Disease burden by possible waterborne diseases

Selected Notifiable Conditions	# Confirmed Cases	# of Probable Cases	# of Suspect Cases
Amebiasis	39	40	1
Cryptosporidiosis	174	0	4
Giardiasis	743	0	4
Legionellosis	135	0	23
Shigellosis	213	0	2
<i>Vibrio species</i>	53	0	3

All waterborne pathogens identified in the above table are reportable to the Massachusetts Department of Public Health (MDPH) Office of Integrated Surveillance and Informatics Services (ISIS). ISIS enhances and optimizes the collection and distribution of infectious disease surveillance data and promotes standards-based electronic reporting of notifiable disease data by hospital laboratories, electronic health records, and other public health partners. ISIS develops, deploys and maintains the Massachusetts Virtual Epidemiologic Network (MAVEN), and oversees Electronic Laboratory Reporting (ELR) and Health Information Exchange (HIE) efforts as they relate to notifiable disease reporting and surveillance activities.

Massachusetts local public health operates through 351 individual city and town jurisdictions, and most cases of notifiable disease (with few exceptions) are investigated by the local authority in the jurisdiction where the case resides. Information obtained during these investigations is then forwarded to MDPH by a paper case report form or through MAVEN. An MDPH epidemiologist reviews every case looking for clustering or unusual activity.

While the Hinton State Laboratory Institute does not have the capacity to test environmental samples for bacterial waterborne pathogens, it can test clinical samples for bacterial pathogens such as Shigella, Legionella, Vibrio species, etc. that could be transmitted through water. Contracts are in place, however, to perform environmental testing as funding permits.

Building waterborne capacity is a recognized goal. Currently, outbreaks are investigated in the same manner as any communicable outbreak. Outbreaks related to swimming pools, lakes, beaches, ponds, etc. are investigated jointly by the Epidemiology Program and the MDPH, Bureau of Environmental Health's (BEH) Community Sanitation Program (CSP). These relationships are not formalized as they are for outbreaks related to foodborne illness. Established in 1986, the Working Group on Foodborne Illness control (WGFIC) is a collaboration among laboratorians, epidemiologists, and food protection officials that meets a minimum of twice each month to discuss all clusters and outbreaks of foodborne illness in the state.

We propose to spend the first year building capacity by incorporating waterborne activities into the WGFIC and gaining information about chlorine standards in swimming pools as described below.

In Massachusetts, most public and semi-public swimming pools are regulated by the local boards of health (LBOH) under the state sanitary code: 105 Code of Massachusetts Regulations 435.00. The CSP has coordinate powers with LBOHs in enforcing these and other sanitary code requirements, and interprets the regulations and provides related guidance to LBOH. In addition, the CSP has a Memorandum of Agreement with the Massachusetts Department of Conservation and Recreation (DCR) to inspect state-owned swimming pools. A 2001 interpretation by the Massachusetts Attorney General's Office determined that state agencies do not have to comply with the provisions of the state sanitary code; however, the DCR requested the assistance of MDPH in ensuring that state regulatory requirements for pools are met. The regulations require that swimming pool operators maintain a residual chlorine level that is expected to inhibit bacteria growth and the possible transmission of disease and illness. The LBOH can order bacteria tests to be conducted to evaluate the effectiveness of the pool chlorination, but testing for bacterial levels is rarely required or conducted. Thus, there is a data gap on information that would indicate that required residual chlorine levels do in fact result in compliance with established bacterial standards for swimming pools. Addressing this data gap will serve several purposes. First, it will provide data to support the efficacy and sufficiency of current residual chlorine standards protecting against bacterial-related illness in swimming pools. Second, it will provide an economic benefit by demonstrating that residual chlorine testing is sufficient without the need to do regular bacterial testing also. Third, it will help guide future regulatory and operational changes.

MDPH/BEH would oversee the collection of pool water samples from 20 pools: 10 indoor and 10 outdoor pools. Two samples would be collected per pool, one sample when the pool is empty of bathers and one when bathers are present. The samples would be collected from the shallow end of the pool, which would maximize the potential for detecting bacteria due to the presence of

children. The samples would be analyzed for chlorine and *E.coli* and/or coliform and compared to both the swimming pool bacterial and chemical standards (105 CMR 435.28-29) and the bathing beach bacterial standards (105 CMR 445.031). A comparison between the levels of bacteria and free chlorine residuals will assist MDPH/BEH in determining the efficacy of the current standards in outdoor and indoor pools. In addition, MDPH/BEH will gain important information on how variables such as bather load and choice of chlorine impact bacteria and free chlorine residual levels. Information gained from the first year of the project will support additional research and further evaluate the variables known and identified during the project.

The results will be compiled into a report and subsequent conclusions and recommendations will be shared with LBOHs, pool operators, and laboratories. The conclusions and recommendations may also guide the development of additional regulations or a revision of current regulations.

b) Operational Plan

Activity 1: *Expand the activities of the Working Group on Foodborne Illness Control (WGFIC) to include waterborne outbreaks and incidents.*

Year 1(1/1/12-12/31/12):

- The Working Group on Foodborne Illness Control will expand to include appropriate representation from the CSP. This will include those individuals with oversight for swimming pools and bathing beaches.
- Beginning 1/1/12, suspected waterborne incidents and outbreaks will be investigated by the Working Group on Foodborne Illness Control.
- All waterborne outbreaks will be reported to CDC through NORS.

Years 2-5 (1/1/13-12/31/16):

MDPH will expand its capacity for waterborne disease detection, investigation and reporting by possible instituting testing for waterborne pathogens in environmental samples at the Hinton State Laboratory Institute.

Activity 2: *Assess whether current chlorine residuals standards are effective in keeping E. coli below bathing standards.*

Year 1(1/1/12-12/31/12):

- Identify 10 indoor swimming pools and 10 outdoor swimming pools for testing
- Collect two samples per pool, one when empty, one when people are in the pool. Samples will be collected in the shallow end of the pool to maximize the chance of detecting bacterial levels which exceed acceptable standards where young children would congregate.
- Analyze collected sample for *E. coli* and chlorine residual levels
- Compile results into a report with subsequent conclusions and recommendations to be shared with LBOH, pool operators, and laboratories.
- Develop additional regulations or revision of current regulations based on the conclusions and recommendations

Years 2-5 (1/1/13-12/31/16):

Information gained from the first year of the project will support additional research and further evaluate the variables known and identified during the project.

c) Measures of Effectiveness/Measurable Goals:

- By 12/31/12, all swimming pool testing is completed and results are evaluated for future action.
- Waterborne outbreaks are investigated by the WGFIC.
- Representatives from the CSP attend all WGFIC meetings where waterborne outbreaks are discussed.

The following data are collected and available for 2012:

- Number of waterborne disease infections
- Number of identified waterborne outbreaks that are investigated
- Number of WGFIC meetings attended by those with oversight for bathing beaches and swimming pools in Massachusetts
- Percentage of reports submitted to NORS Water surveillance system that are complete
- Time from detection of the waterborne pathogen causing an outbreak to submission to NORS
- Number of health education/promotion materials developed
- Number of promotional materials utilized for health education campaigns and/or trainings.